Mugda Medical College, Mugda, Dhaka
* ESTD-2015 *

MuMC Journal

Volume 02 Number 01 January 2019

Editorial

Original Articles

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MuMC Journal

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Editorial

Laparoscopic Cholecystectomy and Choledocholithotomy With Direct Suture Closure of CBD Without T-Tube — A Safe and Better Option for Patient having Cholelithiasis and Choledocholithiasis

Gall Stones are the most common abdominal reasons for admission to a hospital in a developed as well as developing countries in present time. Presence of stone in common bile duct (CBD) is associated with gall stone in a number of cases saving a few where CBD stone is there without Gall Stone. CBD stones develops in about 10-15% of patients with gall stones and literature suggest that CBD stones encountered approximately in 7-15% of all cholecystectomies.[1,2] Other sites for lodgement of these stones include common hepatic duct, left hepatic duct, right hepatic duct and intrahepatic duct.

Laparoscopic cholecystectomy (LC) is the gold standard treatment for cholelithiasis. ERCP removal of stone from CBD is the gold standard. But for patient having both gallstone and CBD stone there is no such standard method. Laparoscopic cholecystectomy plus laparoscopic choledocholithotomy with direct suture closure of CBD without T-Tube is a safe and better alternative in a patient having both gall stone and CBD stone.

The option available for CBD exploration are ERCP exploration, transcystic exploration , laparoscopic or open choledocholithotomy with direct suture closure without T-Tube drainage. Before closure of CBD, stone clearance is ensured by doing saline test, per-operative cholangiogram or per-operative choledochoscopy. It is essential to provide drainage tube in the sub hepatic space in apposition to CBD. ERCP facilities are not everywhere and always available. Moreover ERCP has its own complications like cholangitis, pancreatitis, perforation etc. After choledocholithotomy T-Tube is given usually. The T-Tube insertion aids in postoperative bile decompression thereby facilitating the visualization and extraction of any residual stone. Other shortcomings includes bacteremia, dislodgement of tube , obstruction and/or fracture of tube.[3] T-Tube drainage is associated with an increased incidence of cholangitis and wound sepsis.[4,5] Furthermore leakage of bile may be encountered after its removal. Other associated complications include inconvenience to the patient due to its placement for a long time and delayed hospital discharge.

The role of T-Tube has been challenged since Thornton and Halsted described primary duct closure after CBD exploration more than a century ago.[7,8] Compared to T-Tube drainage, primary closure has its advantage which include shorter operating time, lesser duration of hospital stay, lower incidence of bile leak and wound infections etc. Hence primary closure of CBD is a relatively safe and feasible treatment procedures compared to T-Tube drainage after laparoscopic choledocholithotomy.

Symptomatic gallstone disease is a very common indication for abdominal surgery.[9] Laparoscopic primary closure of CBD without T-Tube has been advocated by some authors because of the potential complication associated with T-Tube placement.[10,14] In the Peterlin JB, lechleitner RA series, primary closure of choledochotomy laparoscopically was performed in over one third of cases where a choledocholithotomy was used and did not result in any complications.[15] There was no incidence of bile leak, peritonitis, or clinical evidence of retained CBD stones. Patient reported a higher degree of comfort and satisfaction than those in whom T-Tube had been placed. Other authors have had similar result.[16-17]

Both primary closure of CBD and T-Tube drainage after CBD exploration are equally good treatment modalities for uncomplicated choledocholithiasis. However, primary closure of CBD has significantly shorter operating time, lesser duration of stay at hospital and laparoscopic primary closure of the CBD following its exploration is a safer alternative as compare to T-Tube placement.

MuMC Journal 2019; 2(1): 1-2

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Original Article

Near Peer Tutoring (NPT) in Medical Colleges in Bangladesh: A Pilot Project

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Article info
Received : 11-10-18
Accepted : 12-11 -18
No. of Tables : 0
No. of Figure : 03
No. of References : 19

ABSTRACT

Background: *Absolute shortage of teachers of preclinical subjects in Bangladesh is the major problem of medical education as a result disproportionate teacher-student ratio thus low level of teacher-student interaction and teaching-learning (T-L) environment.*

Materials and Methods: *The study was conducted at Mudga Medical College, Dhaka with a view to test the feasibility of Near Peer Tutoring (NTP) approach in under grade medical education system in Bangladesh and to find out a convenient education environment by the participation of the learners, to maximize the output of teaching–learning environment to acquire knowledge and skills and minimize the effects of shortage of teachers. The duration of the study were six months. Ten senior students were selected as NPTs based on academic performances and trained them on T-L by the expert faculties from CME & FAIMER fellows. Each trained NPT conducted 2 small group tutorial sessions according to his/her interest on specific topics. 25 junior students were selected randomly for each session. Performances of NPTs in sessions were evaluated by the independent observers, student and self-assessment using a checklist.*

Results: *The average quality score of the sessions obtained from the student satisfaction was about 4.73 out of 5, by self-assessment was about 4.58 out of 5 and from the Independent observers was about 4.67 out of 5.*

Conclusions: *This study concludes that the Near Peer Tutoring approach is feasible and highly accepted by the students and existing faculties. The science is clear, and the evidence is on the table. The next step is to reach as many medical institutions as we can.*

MuMC Journal 2019; 2(1): 3-7

Keywords:
Near Peer Tutoring (NPT), Teaching-learning (T-L) environment, student satisfaction, self-assessment, learning lesion outside class environment.

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INTRODUCTION

The twenty-first century has seen an unprecedented rise in the global private tutoring market. Many have begun to notice that the conventional teacher-student tutor paradigm is ill suited for the digital age.

According to the General Medical Council's guide for "Good Medical Practice", doctors are expected to partake in active mentoring roles and contribute to the education of other training doctors[1]. This reflects the fact that medical education is an apprenticeship where the vertical transmission of knowledge from peers and colleagues contributes to a large proportion of the necessary clinical training. Therefore, peer teaching skills should be inculcated from an early stage.

The Peer Tutoring Program is intended to provide an additional level of academic support to students wishing to receive help with their courses outside of the classroom environment. It represents a supplement to academic support services provided by the Module/Course Director, Faculty and the Office of Medical Education. Senior students taking on teaching roles benefit not only the tutees and themselves but also the institution. Many teaching fellows have very busy schedules, as they have to balance their time with teaching and with patient care[2]. This means that staff may not have as much time as senior students to answer questions that students may have. Whatever the exact definition, peer tutoring as an extremely beneficial means of teaching youth. According to founder of the International Center for Leadership in Education, near peer tutoring elevates learner engagement, self-esteem, and self-confidence. As students of Imperial College London, they have experienced the benefits of teaching skills in the curriculum, having received lectures on teaching skills in their preclinical years as well as a dedicated course in their penultimate year. They have found that studying adult-learning concepts and a variety of teaching strategies have not only improved our teaching skills, but also helped guide our own learning[3]. Peer-led teaching has been shown to be beneficial for student teachers and learners alike, as well as for an educational organization as a whole[4,5]. There are a multitude of advantages of peer teaching in medical education, thoroughly reviewed by Ten Cate and Durning[5]. First, peer-led teaching is beneficial for students, as it provides a comfortable learning environment to explore and develop understanding of different fields of medicine. Second, peer-led teaching provides significant benefits for the student tutors themselves who are involved in the educational process. Third, placing student tutors in a position of responsibility to teach others provides excellent opportunities to enhance leadership, presentation, and organizational skills, all of which are key elements of clinical practice.

Fourth, teaching exposes the tutor to giving and receiving feedback, both of which are important for improving one's own learning and confidence[6]. These are transferable skills that will ultimately improve medical students' performance in the clinical workforce. Finally, peer-led teaching has benefits for medical faculties or health care organizations themselves. Bangladesh is a densely populated country having a total of 92 medical colleges. Absolute shortage of teachers of preclinical subjects is the major problem of medical education as a result disproportionate teacher-student ratio thus low level of teacher-student interaction and teaching-learning (T-L) environment.

So, the main aim of the study was to test the feasibility of NTP approach in under grade medical education system in Bangladesh and To find out a convenient education environment by the participation of the learners.

METHODS

Study design and settings

This cross-sectional study was carried out with an objective to provide supplementary teaching by introducing near-peer tutoring by academically sound senior volunteering students of the same medical college with a view to maximize the output of teaching–learning environment to acquire knowledge and skills and minimize the effects of shortage of teachers by the guidance of the faculties. The duration of the study was six months from March to August 2016.

Study population and sample size

This pilot study was carried out in the Mugda Medical College in Dhaka. First and second year (first phase of MBBS course) medical student was the students of near peer tutoring and academically sound third/fourth (second phase of MBBS course) year students was the peer tutors. Existing faculties of study medical college who were trained in teaching-learning from CME were independent observer in our study. 10 NPTs (phase-ii students) and 500 junior students (25 students for each session, total 20 sessions), 20 observers were participated in the study. Ten senior students were selected as NPTs from the study medical college based on academic performances and motivation. NPTs were trained as tutors by the expert faculties from CME & FAIMER fellows. The trained NPTs conducted 20 small group tutorial classes for Physiology and Biochemistry and demonstration sessions for Anatomy under this study. Each NPT conducted 2 sessions according to their interests on specific topics. About 25 junior students were selected randomly for each session.

Data collection

Performances of NPTs were evaluated by the independent observer (IO) during these sessions using a checklist & also self-evaluation by themselves using the same checklist. Existing faculties of study medical college who were trained in teaching-learning from CME were observer in our study. The performances of NPTs were assessed also by student's satisfaction survey tools which had been done immediate after each session. Indicators for the observation checklist and the satisfaction questionnaire for junior students were developed based on literature review and consultation with the expert from CME. Thirteen different indicators on quality of organization of the session, lecture materials, lecture delivered by NPTs, NPTs-students interaction, organization of group discussion in the classes were used in both observation checklist and satisfaction questionnaire.

Data analysis

Data were analyzed by SPSS latest version. Performances of NPTs were evaluated by the independent observer, student satisfaction and self-assessment by NPTs, which were expressed by mean score and percentage.

Ethical issues

The study was approved by the Ethical Review Committee (ERC) of Mugda Medical College. Both verbal and written consent was taken from participants. Privacy and confidentiality were maintained throughout the study period by excluding personal identifiers during data collection.

RESULTS

Assessment of the near peer tutoring by the student satisfaction.

Figure-01 shows that assessment of the near peer tutoring by the student satisfaction. The average quality score of the sessions obtained from the student satisfaction was about 4.73 out of 5. A vast majority of the students (98.12%) were also satisfied regarding all the quality indicators of the session [Figure1].

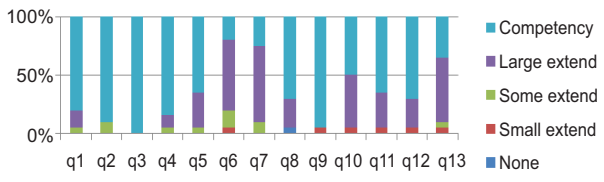

Figure 1: *Assessment of the near peer tutoring by the student satisfaction*

Assessment of the near peer tutoring by the NPTs

Figure-02 shows that assessment of the near peer tutoring by the near peer tutors themselves. The average quality score of the sessions obtained from the NPTs by self-assessment was about 4.58 out of 5 and most of the sessions (93%) were rated as either competent or large extent competent (>3 score out of 5) [Figure 2].

Assessment of the near peer tutoring by the Independent observers

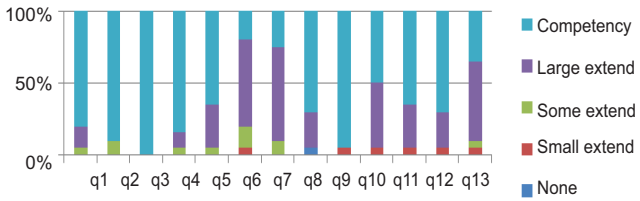

Figure 2: *Assessment of the near peer tutoring by the NPTs*

Figure-03 shows that assessment of the NPT sessions by the Independent observers. The average quality score of the sessions obtained from the independent observers was about 4.67 out of 5. A vast majority of the sessions (97.6%) got >3 scores (competent/large extent) from the Independent observers [Figure-3].

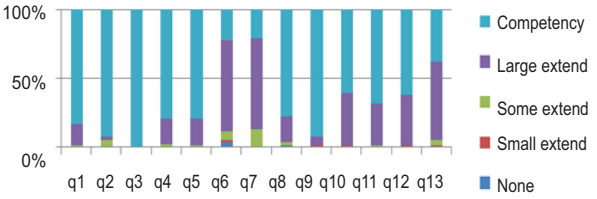

Figure 3: *Assessment of the near peer tutoring by the Independent observers*

DISCUSSION

Near Peer Tutoring has many advantages as an educational method in medical education and Clinical Communication teaching and should be promoted in medical curricula.

From figure1 we find that the average quality score of the sessions obtained from the student satisfaction was about 4.73 out of 5. A vast majority of the students (98.12%) were also satisfied regarding all the quality of the sessions. According to Krych et al, 92% of first-year medical students found that reciprocal peer teaching methods in gross anatomy

teaching improved their communication skills[7]. This is a significant finding, as communication is considered to be vital to the medical profession and has been shown to impact patient satisfaction and adherence to medical treatment[8]. Thus, student tutors benefit by developing leadership, emotional and communication skills.

Another study showed that peer teaching has a primarily impact on both peer teachers and learners. In the settings of problem - based learning courses or clinical skills instruction, medical students' performance on teat of knowledge or skills is similar whether they have faculty instructor peers' teachers. There is also strong evidence that being a peer teacher enhance the learning of the peer teacher relative to the content being taught[9]. Figure-02 shows that assessment of the near peer tutoring by the near peer tutors. The average quality score of the sessions obtained from the NPTs by self-assessment was about 4.58 out of 5 and most of the sessions (93%) were rated as either competent or large extent competent (>3 score out of 5).

A study named Peer tutoring in a medical school: perceptions of tutors and tutees shows that Peer tutoring has been described as "people from similar social groupings who are not professional teachers helping each other to learn and learning themselves by teaching". Peer tutoring is well accepted as a source of support in many medical curricula, where participation and learning involve a process of socialization. Peer tutoring can ease the transition of the junior students from the university class environment to the hospital workplace[11].

Another study about the 'The outcomes and acceptability of near-peer teaching among medical students in clinical skills' shows Tutee perceptions were significantly higher than student-tutor self-perceptions in small-group teaching and facilitation skills (p=0.000), teaching history-taking skills (p=0.046) and teaching physical examination skills (p=0.000). Perceptions in aspects of 'Confidence in tutoring' were not significantly different for student-tutors and tutees, with both having lowest perceptions for identifying and providing remediation for underperforming tutees. Student-tutors rated all areas of personal and professional development highly[12].

Figure-3 shows that assessment of the near peer tutoring by the Independent observers. The average quality score of the sessions obtained from the Independent observers was about 4.67 out of 5. A vast majority of the sessions (97.6%) got >3 scores (competent/large extent) from the Independent observers.

A study showed that almost all medical faculties in Germany actively employ peer tutors. However, little is known about the roles these tutors play from a faculty point of view. Also, there are only few descriptions of the tutor recruitment and selection processes. 32 of the medical faculties in Germany, where tutors are used in the training of medical students, were asked to provide information on the role and recruitment of tutors by means of a partially standardized questionnaire.

At the surveyed faculties (return rate 28 %), tutors are mostly employed for the purpose of teaching staff support. Even though desired in individual cases, tutors rarely play an active role in curriculum- or faculty development. The way tutor recruitment is handled strongly depends on the capabilities of the individual faculties and the way tutors are utilized. In many cases this process is structured, consisting of written and oral application phases, in other cases recruitment takes place without formal application procedures. The selection criteria, however, were found to be very similar at most faculties. The role of tutors from the faculties' point of view depends strongly on the respective nature of the tutorials, which are just as diverse as the approaches to tutor recruitment

A comparative study in law included process measures which indicate that student tutor behaviors were very similar to those of professional faculty. Nevertheless, on outcome test scores the faculty tutored students scored higher than those tutored by peers[10].

CONCLUSION

Near Peer Tutoring of medical education is advantageous and effective, we suggest that peer-led teaching of medical education can be even more effective than professional-led teaching in certain aspects of medical education. Ultimately, we believe it is important to establish a stronger focus on peer-led teaching in medical curricula and, therefore, medical education programs should be adjusted to incorporate this for the benefit of the students, student teachers, and organizations alike. The

average quality score of the sessions obtained from the student satisfaction was about 4.73 out of 5, by self-assessment was about 4.58 out of 5 and from the Independent observers was about 4.67 out of 5. The result is very significant to lead the curiosity of policy makers and researcher to go ahead this internationally recognized beneficial teaching method. The peer teaching program provided a framework within the medical curriculum for senior students to practice and improve their medical knowledge and teaching skills. Concurrently, junior students were provided with a valuable learning experience that they reported as being qualitatively different to traditional teaching by faculty.

RECOMMENDATIONS

Due to increased cognitive and social congruence with their tutees, near peer teachers (NPTs) may be capable of more effectively delivering course material. There is a lack of research on the perceptions of peer tutoring, particularly from tutees who partake in a long-term clinical skills scheme integrated into the medical school curriculum.

This study concludes that the Near Peer Tutoring approach is feasible, fruitful and highly accepted by the students and existing faculties. This reflect that there is a great chance of further scaled up in the medical education of Bangladesh to reduce the gap of teacher student ratio as well as the Teaching learning environment. Further large-scale research is needed for understanding the actual effects and wide spread applications of Near Peer Tutoring in medical education system of Bangladesh.

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Original Article

The Use of Labetalol and Methyldopa in the Management of Preeclampsia

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Article info
Received : 12-8-18
Accepted : 10-10-18
No. of Tables : 02
No. of Figure : 0
No. of References : 11

ABSTRACTS :

Objective : *To compare side effects of labetalol and methyldopa on mother in the management of preeclampsia.*

Materials and Methods: *This (case-control study) was conducted in Obs & Gynae Department of Dhaka Medical College Hospital during the period from January 2012 to June 2012. Two fifty patients who admitted in this hospital were the target population for this study. Patients were selected randomly to use either (Group $A_{=125)}$ Tab labetalol and (Group B -125) Tab methyldopa. Main outcome measure was maternal complications like abruptio placentae, eclampsia and HELLP syndrom .*

Result: *The mean age was found 25.73 years in group A and 26.99 years group B. Primigravida are more predominant in the two groups. Gravida, occupation. Socioeconomic status, residence area were not statistically significant (P› 0.05) between two groups. Spontaneous onset of delivery was found 106(85.0%) in group A and 67(53.6%) in group B. Vaginal delivery patients were found 103(82.4%) in group A and 76(60.8%) in group B. spontaneous onset and vaginal delivery were significantly higher in group A. Abruption placenta was found 1(0.08%) in group A and 4(3.2%) in group B. Eclampsia was found 1(0.08%) and 3(2.4%) in group A and group B respectively. HELLP syndrome was not found in group A and 2(1.6%) was found in group B. . Maternal complications were higher in group B, but not statistically significant (P›0.05).*

Conclusion : *This case-control study was done to compare side effects of labetalol and methyldopa on mother in the management of preeclampsia. The study shows that labetalol is a useful drug in the treatment of preeclampsia and does not seem to have any major side effects on the mother antenatally, during labour or postpartum.*

MuMC Journal 2019; 2(1): 8-11

Keywords: Abetalol, Methyldopa, Preeclampsia
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INTRODUCTION:

Women with elevated blood pressure during pregnancy have a significantly increased maternal and fetal morbidity and mortality. Hypertension affects between 7 and 15% of all pregnancies and is associated with as much as 22% of all prenatal death and 30% of all maternal death. There are multiple possible causes of elevated blood pressure but majority of cases can be divided into 4 well defined groups as chronic hypertension, gestational hypertension, preeclampsia-eclampsia and superimposed preeclampsia

Preeclampsia is a syndrome manifests clinically as new onset hypertension in later pregnancy (Any time after 20 weeks, but usually close to term) with associated proteinurea:1+ on dipstick and officially ›300 mg per 24 hours urine collection. This syndrome

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occurs in 5 to 8% of all pregnancies and is thought to be a consequence of abnormalities in the maternal vessels supplying the placenta, leading to poor placental perfusion and release of factors causing widespread endothelial dysfunction with multiorgan system clinical features such as hypertension, proteinuria, cerebral and hepatic dysfunction.[1,2]

Superimposed preeclampsia complicates 25% of pregnencies in women with chronic hypertension,a much higher risk that observed in the general population.[3] Gestational hypertension occurs in 6% of pregnancies and hypertension developing in the later half of pregnancy not associated with the systemic features PE. Approximately 15% to 45% of women initially diagnosed with gestational hypertension will develop PE that is development of proteinuria and this is more likely with earlier presentation, previous miscarriage and previous hypertensive pregnancy as well as higher BP.[4,5,6]

Preeclampsia during pregnancy posses significant risk to the mother and fetus. Placental abruption is one of dangerous complication of PE.[7] PE also associated with fetal complications like preterm birth, IUGR, still birth and neonatal death.[8] Prevention of cardiovascular and cerebrovascular consequences of severe and rapid elevation of BP is an important goal of clinical management often requiring judicious use of antihypertensive medication. Therefore the diagnosis of PE is very important. Once it is diagnosed, the obstetrician should manage the patient in collaboration with neonatologist. The goal should be to achieve an optimum blood pressure control as early as possible to prevent complication. So in the management of preeclampsia methyldopa and labetalol are used. Here we used labetalol to group A and methyldopa to group B to see the effective blood pressure control. So purpose of this study was to explore any major side effects of labetalol and methyldopa on mother during controlling blood pressure.

Materials and methods:

This case-control study was conducted in the indoor of obs and gynaecology department of DMCH, Dhaka.

During the period of January to June 2012, preeclampsia patients in obstetrics and gynaecology indoor in DMCH, a total 250 patients(125 labetalol group and 125 methyldopa group) were randomly selected. Only preeclampsia and singletone pregnancy cases were included. Exclusion criteria were, patients with chronic hypertension, renal disease, any other medical disorders and multiple pregnancies.

125 patients were managed by highest doses(400 mg) of labetalol in two divided doses. Another 125 patients were managed by highest doses of methyldopa (1000 mg) in 4 divided doses. The variables included in the study were age, socioeconomic status, parity, gravidity, abruptio placentae, eclampsia and HELLP syndrome. After editing and coding, the coded data was directly entered into the computer by using SPSS software release for windows version 16.Data cleaning validation and analysis was performed using the SPSS software. Categorical data was presented as frequency, percentage and continuous variable was expressed as mean ±SD (standard deviation).

RESULT:

During the study periods total of 250 subjects were studied of which 125 were managed by labetalol (group A) and 125 were managed by methyldopa (group –B).There was no difference in age, social class, occupation and gravidity between the groups (Table-1). . Abruption placenta was found 1(0.08%) in group A and 4(3.2%) in group B. Eclampsia was found 1(0.08%) and 3(2.4%) in group A and group B respectively. HELLP syndrome was not found in group A and 2(1.6%) was found in group B. Maternal complications were higher in group B, but not statistically significant(P›0.05).

A total of 250 patients were included in this study and they were divided into three groups according to age. Majority of the patients was found belonged to<20 years in both groups, which was 88(70.4%) in group A and 69(55.2%) in group B. The mean age was found 25.73 years in group A and 26.99 years in group B. The mean age difference was not statistically significant(p>0.05) between two groups. Primigravida are more predominant in two groups.Maximum 112(89.6%) and 108(86.4%) were housewife in group A and group B respectively. Majority 99(79.2%) patients in group A and 94(75.2%) in group B came from low socioeconomic status. Gravida, occupation and socioeconomic status were not statistically significant (P>0.05) between two groups in chi square test.

Table 1: Socio demographic characterized (n=250).

Socio demographic Characterized	Group I (n=125)		Group II (n=125)		*P* value
Age (years)	n	%	n	%	
≤20	88	70.4	69	55.2	
21-30	22	17.6	17	13.6	
>30	15	12	39	31.2	
Mean ± SD	25.73±4.64		26.99±5.48		$^{a}0.056^{ns}$
Range (min-max)	18-35		18-36		
Gravida					
Primi	85	68.0	79	63.2	$^{b}0.424^{ns}$
Multi		40	32.0	46	36.8
Occupation					
Housewife	112	89.6	108	86.4	$^{b}0.436^{ns}$
Service holders	13	10.4	17	13.6	
Socioeconomic status					
Low	9	79.2	94	75.2	$^{b}0.451^{ns}$
Middle/High	26	20.8	31	24.8	

Group A labetalol
Group B-Methyldopa
s=significant, ns=not significant
aP value reached from unpaired t-test
bP value reached from chi test

Table 2: *Maternal complication of the study patients (n=250)*

Complications	Group I(n=125)		Group II(n=125)		*P* value
	n	%	n	%	
Maternal					
Abruptio placenta	1	0.8	4	3.2	0.175^{ns}
Eclampsia	1	0.8	3	2.4	0.310^{ns}
HELLP syndrome	0	0	2	1.6	0.155^{ns}

ns=not significant
p value reached from chi square test.

The above table shows the maternal complications of the study patients. Abruptio placenta was found 1(0.8%) in group A and 4(3.2%) in group B. Eclampsia was found 1(0.8%) and 3(2.4%) in group A and group B respectively. HELLP syndrome was not found in group A and 2(1.6%) in group B. The difference was not statistically significant (P>0.05) between two groups in chi square test.

DISCUSSION:

Preeclampsia is a multisystem disorders with complex pathogenesis which is not completely understood. Control of blood pressure and prevention of complication such as eclampsia is one of the most important parts of management. There is now conclusive evidence that the best available antihypertensive for women who have had preeclampsia is labetalol.

Bangladesh is a developing country where the incidence of preeclampsia is very high and eclampsia remains the leading cause of death in large tertiary level hospitals like Dhaka Medical College Hospital

for many years. Most of the preeclampsia occur in nulliparous women.[9]

A total of 250 patients with preeclampsia having no medical or obstetrical complications who admitted in the department of obstetrical and gynaecology Dhaka Medical College Hospital, Dhaka during the period of January 2012 to June 2012 were included in this study. Majority of the patients was found belonged to <20 years in both group. Primigravida are more predominant in the two groups. Most of the subjects of both groups were housewife. Socioeconomic status of most of study subjects of both groups were low. Gravida, occupation, socioeconomic status were not statistically significant (P>0.05) between two groups in chi square test. In this randomized controlled trial study it was observed that abruptio placenta was found 0.8% in group A and 3.2% in group B. Eclampsia was 0.08% and 2.4% in group A and group B respectively. HELLP syndrome was not found in group A but 1.6% found in group B. Kanto(1985) mentioned in his study that the main side effects of labetalol are fatigue, headache, postural hypotension and it can worsen bronchial asthma .[10] In another study, EI-Qarmalawi et al, (1995) mentioned that there was one case of abruptio placenta treated with labetalol and none in patients treated with methyldopa.[11] On the basis of the results of the study it could be concluded that side effects of labetalol and methyldopa is not statistically significant. But advantage of labetalol which taken in two divided doses but methyldopa taken in four divided doses which causes difficulties of patients. However, a large scale study needs to be concluded to reach a definitive conclusion.

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Original Article

Outcome of Accommodation exercise in Treatment of Eye ache during Reading

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Article info
Received : 09-10-18
Accepted : 12-11-18
No. of Tables : 04
No. of Figure : 01
No. of References : 13

Keywords: Eye ache
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ABSTRACT

This study was conducted at Ispahani Islamia Eye Institute and Hospital, Dhaka, during the period of Jan' 2013 to Dec' 2013. Fifty patients with symptoms of eye ache were included in this study. Complete clinical and orthoptic examination with medical history was taken. The mean age was 12.14 ± 1.71 years (range 9-15 years). Majority of patients were students. The mean NPC (near point of convergence-is a measurement of how close one can bring a fixation target to the nose while maintaining fusion)at first visit was 11.47± 1.23 cm. The mean positive fusional vergence for near was 16.17± 2.63 Ä. The most complained symptom was headache followed by eye ache then blurring of vision. At the end of 3 months only 36 patients (72%) came for follow up after doing pen exercise. At 3 months visit the mean NPC was 9.09 ± 1.52 cm, the mean positive fusional vergence for near was 25.54± 7.34 Ä. Out of 36 patients, 12 patients (33.3%) got complete cure from symptom, while 21 patients (58.33%) got improvement and only 3 patients (8.33%) got no improvement at all.

MuMC Journal 2019; 2(1): 12-16

INTRODUCTION

The clinical importance of eyeache during reading has been recognized from the time of Von Graefe (1862) and it is not an uncommon condition. From the time of recognization it is constantly called into play and is indispensable for the maintenance of binocular single vision for all distances optically nearer than infinity and its failure is of great clinical importance. Eyeache during reading is the inability to obtain and/or maintain adequate binocular convergence for any length of time without undue effort.[1] It may be primary or secondary. Predisposing causes inclides wide interpupillary distance (IPD),occupations using mainly distance vision, occupations using mainly uni ocular vision.Illness, ocular fatigue from prolonged close work and poor lighting, exams, advancing age, drugs, pregnancy precipitates the condition.[2]

Heterophoria (convergence weakness exophoria), poor accommodation, refractive error (acquired myopia, high hypermetropia, high anisometropia), vertical deviation, surgery (weakened medial rectus).[2] It is one of the most frequently found causes of ocular discomfort and asthenopia. The prevalence of eyeache during reading is reported to be from 2.25 to 8.3% in the general population, and clinically significant has been found in 13 to 17% of children presenting for eye examination.[3-4] It is a common vision disorder that affects about 5% of school aged children and is associated with symptoms such as visual fatigue, headaches, eye ache, burning eye, blurry letters, doubling of images, floating of words on page and watering when reading and studying.[5-7] Clinical signs includes receded near point of convergence (6cm to 8cm is considered as normal),

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reduced positive fusional vergence, exophoria greater at near and low AC/A.[8]

The near point of convergence (NPC) is the nearest point on which the eyes can maintain binocular fixation. It can be measured with the RAF rule which rests on the patient's cheeks. A target is slowly moved along the rule towards the patient's eyes until one eye loses fixation and drifts laterally (objective NPC). The subjective NPC is the point at which the patient reports diplopia. Normal NPC should be nearer than 10 cm without undue effort.[9]

The near point of accommodation (NPA) is the nearest point on which the eyes can maintain clear focus. It can also be measured with the RAF rule. The patient fixates a line of print, which is then slowly moved towards the patient until it becomes blurred. The distance at which this is first reported is read off the rule and denotes the NPA. The NPA recedes with age; when sufficiently far away to render reading difficult without optical correction, presbyopia is present. At the age of 20 years the NPA is 8 cm and by the age of 50 years it has receded to approximately 46 cm.[9]

MATERIAL AND METHOD

Hospital based prospective longitudinal study

This study was done in the Orthoptic clinic of Paediatric & strabismus department in Ispahani-Islamia Eye Institute and Hospital.

This study was carried out for one year extending from January'2013 to December'2013.

Fifty patients of Convergence Insufficiency were taken as subject of the study.

The sample size was determined by the following formula-

Where,

n= the desired sample size which would help to measure the different indicators.

z= the standard normal deviate, usually set at 1.96 at 5% level which corresponds to 95% confidence level.

p= the assumed target proportion to have a particular characteristics, here, p=0.1

q= 1-p=0.9

If is supposed that, is the relative error of estimate, is to be tolerated with *P*, as proportion in the population.

P, as proportion in the population and d is the degree of accuracy level considered as 5%. The degree of accuracy d, which assume, is 0.05. Putting the values in the above equation the sample size n is estimates as = 138.29

n= 138 (targeted sample size)

The total duration of the study was 15 months and the population size was roughly estimated 90 if N is less than 10,000 the required sample size would be smaller. In this case final sample estimated (n_f) by using the following formula-

(final sample size estimated)

Where,

n_f= the desired sample size, when population is less than 10,000

n= the desired sample size, when population is more than 10,000

N= the estimate of population size.

Total 50 patients attending in the Orthoptic clinic of Paediatric and strabismus Department of Ispahani Islamia Eye Institute & Hospital were enrolled in this study.

Patients under study were explained in details about the disease process, benefits of evaluation, method and risk of evaluation techniques and then written consent was taken before conducting the study.

The patients were selected from orthoptic clinic of Paediatric & strabismus department of Ispahani Islamia Eye Institute and Hospital. Total 50 cases having diabetes with ocular motor nerve palsy of varying severity were included in this study.

Prism bar method

Distance: Diverged to 12" BI/recovered at 9" BI
Converged to 32" BO/ recovered at 21" BO

Near: Diverged to 14" BI/recovered at 9 " BI
Converged to 36" BO/recovered at 24" BO

Convergence insufficiency was treated in Orthoptic clinic of Paediatric strabismus department

Data were be analyzed by computer with the help of SPSS (Statistical Package for Social Sciences) win 13 software package. Statistical analyses were done by using appropriate procedure. Statistical significance is set at 0.05 level and confidence interval at 95% level.

RESULTS

Out of 50 patients involved in this study, only 36 patients (72%) came for follow up after complete accommodation exercise. The mean age of the female patients was 12.22 ± 1.37 years and that of male was 12.06 ± 2.06 years (Table –I, II).

Table-1 : *Sex distribution of convergence insufficiency patient(n=50)*

Sex	Mean Age
Female	12.22 ± 1.37
Male	12.06 ± 2.06

Table-2: *Age distribution of the Patients*

Age Range	Number of patient	Percentage
9 to 11	16	32 %
12 to 15	34	64 %
Total	50	100 %

Majority of patients with eyeache during reading were students (90%) followed by others. The mean near point of convergence at first visit was 11.47±1.23 cm while it was 9.09±1.52 cm after accommodation exercise on follow up visit of 12 weeks. All patients had a poor convergence before the accommodation exercise but 17patients (34%) of the total patients had normal convergence after accommodation exercise. Some amount of eyeache was improved in all the patient, however, convergence was improved by 3-4 cm in about 10 patients (27.7%) of the patients. Only 3 patients (8.33%) improved 5-7 cm(Table-III).

Table-3: *NPC Improvement range after three month of pen exercise*

Number of Patients	NPC range(cm)
17	1 t0 2
10	3 to 4
3	5 to 7

Thirteen patients(26%) cured after accommodative exercise was 16.17Ä. Thirteen patients (36%) had got PFV in normal limit after exercise. The mean PFV on follow up of 12 weeks was 25.54Ä . Nine patients (27%) PFV improved by more than 15Ä.

The most complained symptom was headache with symptom score is 15 followed by eye ache with symptom score is10 then blurring of vision (Table-IV).

Table-4: *Symptomatic improvement in relation with eyeache and fusional amplitude improvement*

Title	Symptom (%)	Eyeache (%)	Fusional Amplitude(%)
Cured	12(24%)	17(34%)	13(26%)
Improved	21(42%)	11(22%)	15(30%)
Not improved	3(6%)	8(16%)	8(16%)
Lost	14(28%)	14(28%)	14(28%)
Total	50(100%)	50(100%)	50(100%)

Figure-1:

DISCUSSION

This study was done in the orthoptic clinic of paediatric & strabismus department of Ispahani Islamia Eye Institute & Hospital, Dhaka. Patients coming in this hospital at the to 15 years with the complains of headache, eye ache or blurring vision with or without refractive error are send to orthoptic clinic . From them diagnosed case patients are isolated. Out of them 50 patients are selected randomly who fulfils the selection criteria, included this study.

Selected patients are prescribed for accommodation exercise at home at least 15 minutes / day and follow up at 4 weeks, 12 week and 24 weeks. It is a simple, cost free and easily taught procedure that involves fewer follow up visit than does office based therapy (12 visits in 12 weeks), therefore convergence exercise is the most commonly prescribed treatment for symptomatic convergence insufficiency.

Out of 50 patients, only 36 patients (72%) came for follow up at 12 weeks after complete convergence exercise 15 minutes per day. Ten patients are lost in

2nd visit and four patients are lost in 3rd visit. This shows poor compliance rate. This may be due to improvement of symptoms which may make the patients reluctant about follow up visit.

This study shows that thirty two patients (64%) were female which indicates more prevalence of female. Similar results were found in other studies[10] where the number of females was more than that of males. Similar results also found in study done by K Sapkota et[11] where they shows that about three fourths of the patients were female which indicates more prevalence of female for eyeache. However, in a study done in Korea by Kim et al,[12] this was just opposite which was male : female =10: 6. This may be due to small number of sample size, which give contradictory finding in different study.

Out of total,45 patients(90%)were students which indicates that eyeache is seen more in people involved in near work and fine work. Similar results founds in study done by K Sapkota et al[11] where they shows out of total, 73% were students and 9% were tailors.

In this study patients, the mean near point of convergence(NPC) at first visit was 11.47±1.23 cm while that was 9.09±1.52 cm at twelve weeks of follow up with statistically significant difference (p<o.oo1). It has also shown that 17 patients (47.2%) had got NPC of normal value after accommodation exercise in 12 weeks. So it shows that the accommodation exercise is beneficial in improvement of eyeache during reading. Although, all showed some improvement, twenty seven percent showed improvement by 3-5 cm which is clinically significant. Similar results were found in a study done by Kim KM and coworkers[12] in Korean population. The initial mean near point of convergence(NPC) of 18.58±7.46 cm improved to mean NPC of 11±4.61 cm after accommodation exercise of 12 weeks. Gallaway and coworkers,[13] in a pilot study, also found that NPC improved in almost all patients with pen exercise..

In my study, the mean positive fusional vergence (PFV) at first visit was16.17±2.63 Ä. After accommodation exercise 13 patients (36.11%) had got normal PFV (>25 Ä being Normal) with mean value of 25.54±7.34 Ä(p<0.001). The improvement by 2-10 Ä was found in most of the cases. It clearly shows that accommodation exercise is efficacious in improving fusional vergence. These findings are similar to the findings of other studies done in USA and Korea by Gallaway et al[13] and Kim et al[12] respectively.

At twelve weeks visits, out of 36 patients, 12 patients became totally symptoms free, 21 patients had partial improvement and 3 patients had no improvement. In case of near point of convergence, 17 patients had their NPC within normal limit, 11 patients had partial improvement and 8 patients had no improvement. In case of fusional amplitude for near, 13 patients became within normal limit, 15 patients had partially improved and 8 patients had no improvement. It has been seen that those patients who are strictly adhere with the accommodation exercise do well than who are not.

CONCLUSION

Convergence insufficiency(CI) is common in young age girls, mostly students with headache as a major complaint. Accommodation Exercise is easier and low cost therapy efficacious for symptomatic eyeache. It improves the NPC and reduces the symptoms of the patients.

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Original Article

Patient profile and findings of first 200 cases of Upper Gastrointestinal endoscopic procedure at Mugda Medical College hospital – A prospective study.

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Article info
Received : 01-02-18
Accepted : 29-12-18
No. of Tables : 3
No. of Figure : 2
No. of References : 17

ABSTRACT:

Thus Upper Gastrointestinal endoscopy (UGIE) has become an established mode of investigation with added opportunity for treatment of a wide range of upper gastrointestinal conditions and biopsy of lesions for diagnosis. The aim of the study was to assess frequency and distribution of endoscopic findings referred from different department including outdoor and indoor of various specialty. A prospective observational study was done. A total of 200 patients referred for endoscopy at endoscopy unit of gastroenterology department of Mugda Medical College Hospital from April'2018 to November 2018 were purposively included. Out of 200 patients 130 referrals were from outdoor, 2 from general practitioner, 24 from medicine indoor, 32 from gastroenterology indoor, 12 from surgery and orthopedic indoor. Symptoms of the 200 patients referred for endoscopy are dyspepsia 35 (31.25%), abdominal pain 25 (22.32%), haematemesis and/or melena 20 (17.85%), heartburn 10 (8.9%), chronic liver disease 10(8.9%), anaemia 5(4.46%), dysphagia 3(2.67%), vomiting 3(2.67%), corrosive poisoining 1(0.89%). Findings of the upper GI endoscopy showed normal findings in 88(44%), gastritis 32(16%), oesophageal varises 20(10%), duodenal ulcer 10(5%), gastric ulcer 12(6%),gastric polyp 8(4%), congestive gastropathy 6(3%), gastric outlet obstruction 6(3%), oesophageal moniliasis 6(3%), duodenitis 4(2%), reflux oesophagitis 4(2%), oesophgeal ulcer 4(2%), oesophageal polyp 2(1%). Dyspepsia was main reason for referral, but the majority of such patients had normal findings. Gastritis and duodenal ulcer was the most common findings. The next was oesophageal varices and congestive gastropathy followed by gastric polyp and oesophageal polyp and dudenitis. Considering the invasiveness of procedure endoscopy should be done with prior specialist consultation.

MuMC Journal 2019; 2(1): 17-21

Keywords:
Gastrointestinal tract, Upper GI Endoscopy, Referral, Endoscopic findings.

INTRODUCTION

The first gastroscopy in 1868 is credited to Kussmaul.[1] This was followed in the 1920s by the conceptualization of image transmission using flexible quartz fibers a concept used by Hopkins in 1954 to build a model of a flexible fibre imaging device the precursor of fibre-optic endoscope.[2] Since then endoscopes and endoscopy have undergone great technical developments to the current new dimension in imaging of endoscope.[3] These developments have enhanced the safety and diagnostic yield of endoscopy as well as providing therapeutic options making upper gastrointestinal endoscopy (UGIE) the most accurate and cost effective tool for evaluating patients with gastrointestinal related symptoms.[4]

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Thus UGIE has become an established mode of investigation with added opportunity for treatment of a wide range of upper gastrointestinal conditions and biopsy of lesions for diagnosis.[5] Direct examination of the mucosal surface provides far greater information than that gained by 2-dimensional scans and x-rays. EGD affords an excellent view of mucosal surfaces of the esophagus, stomach, and proximal duodenum. Upper gastrointestinal (UGI) diseases are leading causes of morbidity and mortality globally. One of the major indications UGIE is dyspepsia. Most patients referred for endoscopy complain of symptoms that come under the general heading of dyspepsia. Gastrointestinal symptoms are responsible for about 10% of the work of general practitioners with upper abdominal symptoms (principally dyspepsia) accounting for about half.[6]

Other indications are dysphagia, odynophagia and gastrointestinal bleeding.[7] The diseases most commonly sought by endoscopy are reflux oesophagitis (and its complications), oesophageal varices, oesophageal cancer, gastric ulcer, gastric cancer, duodenal ulcer, and coeliac disease.

UGIE has been found to be both effective and a safe procedure that can be performed at large medical centers, small rural hospitals, outpatient clinics or even private offices.[7]

Upper gastrointestinal endoscopy (UGIE) was introduced in Mugda Medical College Hospital in April' 2018, since then many patients have undergone the procedure, mainly for diagnostic purposes. However, the cost of the procedure is high and out of reach of many patients. We therefore, reviewed endoscopy records to provide information on clinical indications for the procedure to guide care and inform referral of patients with GI symptoms by the care providers. The objectives of this study were, first, to describe the age and sex distribution of patients referred for UGIE and secondly, to determine the source of referral, indications and endoscopic diagnoses in 200 patients in Mugda Medical College Hospital .

Materials and methods:

A prospective observational study was done. A total of 200 patients referred for endoscopy at endoscopy unit of gastroenterology department of Mugda Medical College Hospital from April'2018 to November 2018 were purposively included in this study aged 19 years and above .All subjects gave written informed consent and the study protocol was approved by the Institutional Ethics Committee. Exclusion criteria were patient with severe shock ,unfit patient like severe anemia, severe respiratory disease, electrolytes imbalance, cardiac causes like recent myocardial infarction, unstable angina, cardiac arrhythmia. Endoscopy was performed by gastroenterologists . Data were collected by medical officer and assistant register on a prestructured questionnaire. Data analysis was done using MS Excel.

RESULTS:

A total of 200 patients referred for upper GI endoscopy were included in this study. Male female ratio 45:55. Age range19-91, median age 52 years.

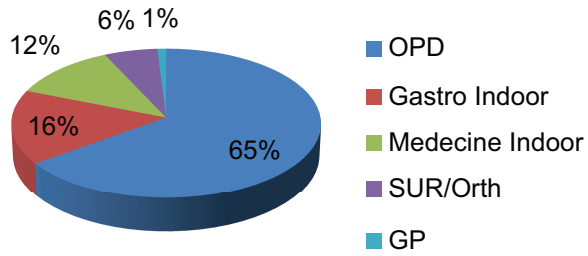

Fig.-1: *Distribution of patients referral from different sources(n=200)*

Figure:1 130 (65%) referrals were from outdoor, 2(1%) from general practitioner, 24(12%) from medicine indoor, 32(16%) gastroenterology indoor, 12(6%) surgery and orthopedic indoor.

Table 1. *Distribution of patients by age group and sex (n=200)*

Age (in years)	Male	Female	Total
19-30	20(10%)	30(15%)	50(25%)
31-40	22(11%)	28(14%)	50(25%)
41-50	20(10%)	38(19%)	58(29%)
51-60	18(09%)	20(10%)	38(19%)
61-70	04(02%)	04(02%)	08(04%)
71-80	00	06(03%)	06(03%)
81-90	04(02%)	02(01%)	06(03%)
91+	02(01%)	02(01%)	04(02%)
Total	90(45%)	110(55%)	200(100%)

Table 1 Male female ratio 45:55, female patient of 41-50 years age (19%) group was most prevalent, followed by female of 19-30 years age group (15%), male of 31- 40 years age group (11%).

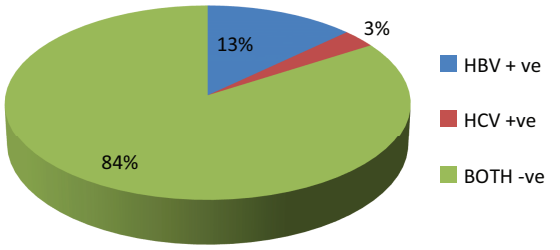

Fig.-2. *Distribution of patients on the status of HBV and HCV Positivity (n=200)*

Figure:1 HBsAg and Anti HCV negative in 168(84%), HbsAg was positive in 26 (13%), Anti HCV positive in 6(3%) of patients.

Table II. Distribution of patients on the basis of presenting complaints (n=200)

Complaintsof patients	Total number	Percentage (%)
Dyspepsia	35	31.25%
Abdominal pain	25	22.32%
Haematemesis and/ malena	20	17.85%
Heartburn	10	8.9%
CLD	10	8.9%
Anaemia	5	4.46%
Dysphagia	3	2.67%
Vomiting	3	2.67%
Corrosive poisoining	1	0.89%

Table: II Presenting complaints were dyspepsia 35(31.25%), abdominal pain 25(22.32%), haematemesis and/or melena 20(17.85%), heartburn 10(8.9%), Chronic liver disease 10(8.9%), anaemia 5(4.46%),dysphagia 3(2.67%), vomiting 3(2.67%), corrosive poisoining 1(0.89%).

Table-III. *Distribution of patients on the basis of Endoscopic findings(n=200)*

Finding	No. of patient	Percentage
Normal	88	44%
Gastritis	32	16%
Oesophheal vrix(OV)	20	10%
Duodenal ulcer	10	5%
Gastric polyp	6	3%
Gastric ulcer	6	3%
Congestive gastropathy	6	3%
Gastric Outlet Obstruction (GOO)	6	3%
Eosophageal moniliasis	6	3%
Carcinoma Stomach	4	2%
Duodenitis	4	2%
Reflux oesophagitis	4	2%
Oesophageal polyp	4	2%
Oesophageal ulcer	4	2%
Total	200	100%

Table III. Findings of the upper GI endoscopy showed normal findings were 88(44%), gastritis 32(16%), oesophageal varises 20(10%), duodenal ulcer 10(5%), gastric ulcer 12(6%), gastric polyp 8(4%), congestive gastropathy 6(3%), gastric outlet obstruction 6(3%), oesophageal moniliasis 6(3%), duodenitis 4(2%), reflux oesophagitis 4(2%), oesophgeal ulcer 4(2%), oesophageal polyp 2(1%).

DISCUSSION :

A total of 200 patients referred for upper GI endoscopy were included in this study. Age range 19-91, median age 52 years. In this study 55% of the patients were female and the rests were male. This sex distributions were quite normal for Bangladesh. The median age of the patients was 52 years. Among female; patient of 41-50 years age (19%) group was most prevalent, followed by female of 19-30 years age group (15%), among male patients 31- 40 years age group (11%) was common. These findings were also quite normal as the dyspepsia and abdominal pain may occur in early part of adulthood. Open-access endoscopy (OAE) is defined as the performance of endoscopic procedures requested by referring physicians without a previous clinic

consultation. Traditionally, physicians have requested consultations for their patients by an individual who performs endoscopy to determine whether endoscopic intervention was indicated[7,8] 130 patients referrals were from outdoor, 2 from general practitioner, 24 from medicine indoor, 32 gastroenterology indoor, 12 surgery indoor and orthopedic indoor. Symptoms of the 200 patients referred for endoscopy were dyspepsia 35 (31.25%), abdominal pain 25 (22.32%), haematemesis and/or melena 20 (17.85%), heartburn 10 (8.9%), chronic liver disease 10(8.9%), anaemia 5(4.46%), dysphagia 3(2.67%), vomiting 3(2.67%), corrosive poisoning 1(0.89%). In our study dyspepsia is the commonest indication for endoscopy in this group of patients, followed by abdominal pain, hematemesis and/or melena, heart burn and chronic liver diseases(CLD) . We found that 31.25% of the patients were referred because of dyspepsia, a finding which is in agreement with other published findings. Taye *et al*.[9] in a review of 10,000 endoscopies in Ethiopia between 1979 and 1994 showed that 59.4% were referred because of dyspepsia, whereas in Nigeria in 2009, 61% of patients undergoing endoscopy had dyspepsia. Our second indication is abdominal pain which is in agreement with other published findings Adful *et al.*[10] Among the referred 200 patient both HBsAg and Anti HCV was negative in168(84%), HBsAg was positive 26(13%), Anti HCV was positive 6(3%). Normal findings were found in the majority (44%) of the patients. This is not surprising as the prevalence of non- ulcer dyspepsia has been reported to be high.[11] It can therefore be argued that the prevalence of normal endoscopy findings in symptomatic patients parallel that of non ulcer dyspepsia. This view is supported by many publications reporting consistently high prevalence of between 41% to 52% of normal endoscopy findings among different populations and age groups.[11,12,13] We found gastritis 32(16%), duodenal ulcer 10(5%), gastric ulcer 12(6%). The world over, peptic ulcer disease (PUD) is one of the major diagnoses made on patients with dyspepsia. Our findings are at variance with those from other countries. In one study from India DU was seen in only 10.9%.[14] We also found oesophageal varises 20(10%),congestive gastropathy 6(3%), oesophageal moniliasis 6(3%), which is common in medicine and gastroenterology indoor patient as their indication was CLD, haematemesis, melena which is similar as reported by *Adegboyega Akere et al*.[15] other findings were gastric polyp 8(4%), oesophageal polyp 2(1%), findings which is an agreement with other published findings. *Rafiul Sameer Islam at el*.][16] Gastric outlet obstruction 6(3%), duodenitis 4(2%), reflux oesophagitis 4(2%), oesophgeal ulcer 4(2%) were other findings which also common in this part of the world. The frequency of diagnosis in a series of 1575 patients seen consecutively in IGE between September 2007 and May 2008 showed reflux oesophagitis and hiatal hernia (31.6%), duodenitis (31.1%).[17]

LIMITATIONS OF THE STUDY:

The study was conducted for limited period, sample size also small. Certainly a multicentre and wider study conducted in different hospital setting would reveal more information, but due to time and resource constrain more elaborate study could not be done.

CONCLUSION:

Dyspepsia was the main reason for referral, but the majority of such patients had normal findings. Gastritis and duodenal ulcer is the most common findings. The next was esophageal varices and congestive gastropathy followed by gastric polyp and esophageal polyp and duodenitis. Considering the invasiveness and cost of procedure, upper GI endoscopy should be done with prior specialist consultation.

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Original Article

Serum Uric Acid Level in Acute Stroke Patient: Study of 100 Cases

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Article info
Received : 17-07-18
Accepted : 19-09-18
No. of Tables : 07
No. of Figure : 0
No. of References : 32

ABSTRACT

The role of serum uric acid (SUA) levels as an independent risk factor for vascular disease has been questioned for decades. Evidence from epidemiological studies suggests that elevated SUA levels may predict an increased risk for cardiovascular (CV) events, including stroke[1-5]. Hyperuricaemia has long been associated with cardiovascular disease, hypertension, metabolic syndrome, and renal disease[6]. The study was conducted at Dhaka Medical College Hospital from July 2010 to December 2010. One hundred first time stroke patients were included in this study ; both male and female (non-pregnant) who fulfill the inclusion criteria. It was a prospective observational study. Purposive sampling technique was used. Fifty nine percent of the patients were male and the rests were female. About 85% of them were Muslim. The mean age of the patients was 62.3 years with a SD ± 9.078 years. Patients from the age group 51-60 years formed the main bulk followed by 61-70 years group (36% and 33% respectively). The mean value of serum uric acid was found as 7.108 mg/dl (SD ± 2.292) which was clearly above the normal limit. The mean value of Random Blood Sugar was 7.45 mg/dl with SD ± 3.292 (n=86) and for Serum Creatinine the mean and SD value were 0.898 and 0.2108 respectively which are within normal limit. Lipid profiles were checked in 93 patients. It was shown that the Cholesterol level was much higher than normal value but other parameters were somewhat normal. About half of the male respondents were hypertensive, the prevalence of hypertension in female was little more than their male counterpart. The study revealed that about 24% of all male stroke patients were suffering from DM whereas females were 17% .This difference was not statistically significant. In both sexes, left sided hemorrhagic CVD topped the tally followed by right sided hemorrhagic CVD. The prevalence of Ischaemic CVD was found to be little lower. The present study suggests that high serum uric acid levels may be associated with increase risk of stroke incidence and hence, mortality.

MuMC Journal 2019; 2(1): 22-27

Keywords:
Hyperlipidaemia.
Hyperuricaemia, Stroke

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INTRODUCTION

Stroke entails a high socio-economic burden due to increased morbidity and mortality[7]. Stroke is a non-communicable disease of increasing socioeconomic importance in ageing populations. According to WHO, stroke was the second commonest cause of worldwide mortality in 1990 and, the third commonest cause of mortality in more developed countries; it was responsible for about 4·4 million deaths worldwide. Stroke is also a major cause of long-term disability and has potentially enormous emotional and socioeconomic consequences for patients, their families and health services. Early identification of individuals at risk (patients with diabetes or hypertension) could be of help in designing primary prevention strategies[8] ·Elevated

uric acid levels in the blood, also called Hyperuricaemia, may indicate alcoholism, acidosis, gout, diabetes, lead poisoning, hypoparathyroidism ,kidney stones, leukemia, renal failure, polycythemia vera, toxemia of pregnancy, renal failure, excessive exercise, chemotherapy-related side effects and consumption of a purine-rich diet[9] · A lower than normal level of uric acid in the blood may signify Fanconi syndrome, Wilson's disease, consumption of a low-purine diet or SIADH.[9]

The role of serum uric acid (SUA) levels as an independent risk factor for vascular disease has been questioned for decades[10]. There is no universally accepted definition for hyperuricaemia, but it is usually defined as a serum urate concentration >6.8 mg/dl, which is the limit of urate solubility in serum [11-12]. The exact level of uric acid that is considered too high is a matter for debate. Evidence from epidemiological studies suggests that elevated SUA levels may predict an increased risk for cardiovascular (CV) events, including stroke[1-5]. Moreover, therapeutic modalities with a SUA-lowering potential have been shown to reduce CV disease morbidity and mortality[1-5] .In this respect, SUA levels could be used as an 'easy-to-measure' serum marker in selecting and appropriately treating subjects at risk. As a potentially modifiable risk factor, the prospect for uric acid and its derivatives to play a role in disease modification or prevention has great potential.

Uric acid is primarily produced as an end product of purine metabolism. Dietary purine intake accounts for a smaller percentage of the body's total uric acid production; however, it is more commonly formed from de novo synthesis or degradation of nucleic acids. Uric acid is excreted in the urine[13].

The mechanism by which hyperuricaemia is related to atherosclerotic disease is unclear. One hypothesis is that hyperuricaemia increases stroke risk through its association with stroke risk factors. Hyperuricaemia may perpetuate hypertension by causing renal injury, which disrupts the rennin-angiotensin system[14]. It is also linked to insulin resistance/metabolic syndrome [15] and low HDL cholesterol levels[14]. Direct effects of UA on vascular physiology have also been explored. Elevated UA levels are associated with increased arterial stiffness, endothelial dysfunction and blunted vasodilator response.[16] UA may contribute to endothelial dysfunction by promoting LDL-C oxidation, stimulating granulocyte adherence and promoting macrophage infiltration of the vascular wall[17,18]. Although UA is typically an anti-oxidant some authors have suggested that it can take on pro-oxidant properties under certain conditions.[19] The link between uric acid and stroke is less clear. Some authors have suggested that elevated uric acid levels are closely associated with stroke risk factors and therefore hyperuricaemia is a marker in patients at high risk for stroke[20]. Others contend that uric acid is an independent risk factor for stroke and is directly involved with the pathophysiology of cerebrovascular disease[20]. Even when other cardiovascular risk factors are controlled for, a significant association between stroke and hyperuricaemia remains, indicating that UA levels may be an independent predictor of stroke risk and not just a marker for disease state[21].Worldwide extensive research is conducting on this subject. The present study was undertaken to identify the link between serum uric acid and stroke.

METHODS AND MATERIALS

This is a prospective observational study. A total of 100 patients aged older than 40 years (59% of the patients were male and rest 41% were female) diagnosed as first ever in a life time acute ischaemic/ nonembolic stroke were included in the study.

Criteria for inclusion in the study were - Subjects aged 18 – 80 years, patients admitted in medicine ward of Dhaka Medical College Hospital with first ever Stroke, and non-pregnant female. Exclusion Criteria were -Subjects with a history of vascular disease (previous stroke, angina, myocardial infarction, revascularizations, peripheral artery disease), renal or liver disease, excessive alcohol consumption, neoplasia , stroke patients with a known or possible cardiac source of emboli (atrial fibrillation, heart valve disease, patients receiving anticoagulant treatment). All subjects gave informed consent and the study protocol was approved by the Institutional Ethics Committee. Hypertensive patients were recorded according to medical history and relevant drug treatment. All biochemical analyses were performed by commercially available standardized methods within 24 hour after stroke onset. Laboratory investigation included complete blood count and serum biochemistry (creatinine, urea, electrolytes, uric acid). Blood glucose and lipid

determination were performed after fasting overnight. Data analysis was done using MS Excel.

RESULTS:

Out of 100 patients ,male : female was 59:41; 85 patients Muslim & 15 patients Hindu.

Table 1. *Distribution of the patients by age group*

Age group (yrs)	Frequency	Percent	Mean ± SD
<=40	1	1.0	
41-50	9	9.0	
51-60	36	36.0	62.30± 9.078
61-70	33	33.0	
71-80	21	21.0	
Total	100	100.0	

Patients from the age group 51-60 years formed the main bulk followed by 61-70 years group (36% and 33% respectively). The mean age of the patients was 62.3 years with a SD ± 9.078 years

Table 2. *Distribution of the patients by occupation*

Occupation	Frequency	Percent
Business	21	21.0
Service holder	14	14.0
Retired/Aged person	13	13.0
Farmer	5	5.0
Daily worker	4	4.0
Teacher	2	2.0
Social Worker	2	2.0
Housewife	39	39.0
Total	100	100.0

Large numbers of respondents were businessmen (21%) followed by service holders (14%). A considerable portion of the respondents (13%) were retired from their jobs. Most of the female patients were housewives (39%).

Table 3. Distribution of the patients by status of Diabetes Mellitus with sex

Diabetes Mellitus	Sex				Total	
	Male		Female			
	N	%	n	%	N	%
Diabetic	14	23.73	7	17.07	21	21.0
Nondiabetic	45	76.27	34	82.93	79	79.0
Total	59	100.0	41	100.0	100	100.0

About 24% of all male stroke patients were suffering from DM whereas 17% of the female patients were suffering from the same. This difference was not statistically significant.

Table 4. Distribution of the patients by status of hypertension with sex.

Hypertension	Sex				Total	
	Male		Female			
	N	%	n	%	N	%
Hypertensive	30	50.85	24	58.54	54	54.0
Normotensive	29	49.15	17	41.46	46	46.0
Total	59	100.0	41	100.0	100	100.0

Almost half of male stroke patients were suffering from hypertension and half were not. In female the percentage of hypertensive patients (59%) was higher than normotensives.

Cent percent of the patients underwent test for serum Uric Acid. Mean value was 7.108 mg/dl with SD ± 2.292. The mean value of Random Blood Sugar was 7.45 mg/dl with SD ± 3.292 (n=86) and for Serum Creatinine the mean and SD value were 0.898 and 0.2108 respectively . Out of 100 patients 93 performed the test for Lipid profiles. It was shown that the Cholesterol level was much higher than normal value but other parameters were somewhat normal.

Table 5. Biochemical parameters of the patients

Name of tests	N	Mean ± SD
Serum Uric Acid	100	7.1080 ±2.29242
Random Blood Sugar	86	7.4474 ±3.2927
Serum Creatinine	19	0.8984 ±0.21085
Cholesterol	93	257.98 ±55.491
Triglyceride	93	186.66 ±45.207
HDL	93	37.89 ±18.045
LDL	93	140.08 ±34.79

Table 6. Distribution of the patients by Status of Serum Uric Acid and sex

Serum Uric Acid	Sex				Total	
	Male		Female			
	N	%	n	%	N	%
Positive(>6.8 mg/dl)	35	59.32	23	56.10	58	58.0
Negative	24	40.68	18	43.90	42	42.0
Total	59	100.0	41	100.0	100	100.0

About 59% of all male stroke patients had high serum uric acid whereas 56% of the female patients had the same. Out of 100 patients 58% of the patients got high serum uric acid level.

Table 7. Distribution of the patients by CT scan findings and sex

CT scan	Sex				Total	
	Male		Female			
	n	%	n	%	N	%
Intracerebral Rt sided infraction	13	22.03	9	21.95	22	22.0
Intracerebral Lt sided infraction	11	18.64	11	26.83	22	22.0
Intracerebral Rt sided hemorrhage	15	25.42	8	19.51	23	23.0
Intracerebral Lt sided hemorrhage	20	33.90	13	31.71	33	33.0
Total	59	100.0	41	100.0	100	100.0

In male and female intracerebral left sided hemorrhage topped the list (34% and 32% respectively). In both sexes Intracerebral right sided hemorrhage came next.

DISCUSSION

In this study 59% of the patients were male and the rests were female. About 85% of them were Muslim. Sex and religion distributions were quite normal for Bangladesh. The mean age of the patients was 62.3 years with a SD ± 9.078 years. Patients from the age group 51-60 years formed the main bulk followed by 61-70 years group (36% and 33% respectively). These findings were also quite normal as the Cerebrovascular diseases predominantly occur in the later part of the life.

Uric acid is the end product of purine metabolism in humans. There is no universally accepted definition for hyperuricaemia, but it is usually defined as a serum urate concentration >6.8 mg/dl, which is the limit of urate solubility in serum [22,23] . In the present study mean value of serum uric acid was found as 7.108 mg/dl (SD ± 2.292) which was clearly above the normal limit. This finding is

identical with the Rotterdam study [24]. Out of 100 patients 58% of the patients got high serum uric acid level. The mean value of Random Blood Sugar was 7.45 mg/dl with SD ± 3.292 (n=86) and for Serum Creatinine the mean and SD value were 0.898 and 0.2108 respectively which are within normal limit and in line with some other international studies [9,25] . It is widely believed that hyperlipidemia and hypertension are closely associated with development of stroke in human. To tests this hypothesis lipid profiles were checked in 93 patients. It was shown that the Cholesterol level was much higher than normal value but other parameters were somewhat normal ; about half of the male respondents were the patients of hypertension. The prevalence of hypertension in female was little more than their male counterpart.

High serum glucose level above normal can complicate the situation even more. The study revealed that about 24% of all male stroke patients were suffering from DM whereas 17% of the female patients were suffering from the same .This support association between diabetes mellitus and stroke[26]. About 59% of all male stroke patients had high serum uric acid whereas 56% of the female patients had the same. Out of 100 patients 58% of the patients got high serum uric acid level. In both sexes, left sided hemorrhagic CVD found highest followed by right sided hemorrhagic CVD. The prevalence of Ischaemic CVD was found to be little lower. No statistical significance was found for these variations [7,27].

Limitation of the study

The study was conducted for limited period, sample size also small. Certainly a wider study conducted in different hospital setting would reveal more information; but due to time and resource constrain more elaborate study could not be done. To follow up patients final outcome more time was necessary.

Conclusion

It was proposed in many studies that a high serum uric acid level with or without gout is associated with cardiovascular diseases such as hypertension, coronary heart disease, peripheral vascular disease, and stroke [26,28-32.] Data analysis established that higher serum UA levels were associated with greater stroke burden. The present study suggests that high serum uric acid levels may be associated with increase risk of stroke incidence and, hence, mortality. Further studies are needed to prove whether uric acid has a pathogenetic role in hypertension, vascular disease, atherosclerosis, and stroke. It will also be important to determine whether lowering uric acid levels reduces the frequency of stroke. Future research should focus on confirming the pathogenetic mechanisms of hyperuricaemia as well as examining the role of urate-lowering therapy in stroke.

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Review Article

A Review on Patient Autonomy and Informed Consent: The Core of Principlism

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Article info
Received : 17-10-18
Accepted : 19-11-18
No. of Tables : 0
No. of Figure : 0
No. of References : 69

Keywords:
Principlism, Principle of Autonomy, Informed Consent, Patient Autonomy

ABSTRACT

The most common approach to a clinical ethical analysis is the principlism. According to the principlism, the medical practitioner must attempt to uphold four important principles. Among them, respect for patient autonomy is the most important principle for modern bioethics. Informed consent, in the medical field, is the procedure whereby a patient consents to or refuses (informed refusal) a medical intervention based on the information provided by a health care worker regarding the nature and potential consequences of the proposed treatment regimen. The goal of the informed consent is to respect patient autonomy and enable him to make important decisions regarding his medical care. The principle of autonomy emphasizes that a competent adult always has the right to decide what ought or ought not to be done to them and this is the basis for the practice of "informed consent" in the physician/patient transaction regarding health care. The Principle of Autonomy, its implications on informed consent and patient care situations will be dealt with in this paper.

MuMC Journal 2019; 2(1): 28-38

INTRODUCTION

Ethical choices, both minor and major, confront us everyday in the provision of health care for persons with diverse values living in a pluralistic and multicultural society. In the face of such diversity, where can we find moral action guides when there is confusion or conflict about what ought to be done? Such guidelines would need to be broadly acceptable among the religious and the nonreligious and for persons across many different cultures. Due to the many variables that exist in the context of clinical cases as well as the fact that in health care there are several ethical principles that seem to be applicable in many situations these principles are not considered absolutes, but serve as powerful action guides in clinical medicine.

Some of the principles of medical ethics have been in use for centuries. For example, in the 4th century BCE, Hippocrates, a physician-philosopher, directed physicians "to help and do no harm".[1] Similarly, considerations of respect for persons and for justice have been present in the development of societies from the earliest times. However, specifically in regard to ethical decisions in medicine, in 1979 Tom Beauchamp and James Childress published the first edition of Principles of Biomedical Ethics, now in its seventh edition (2013), popularizing the use of

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principlism in efforts to resolve ethical issues in clinical medicine.[2] In that same year, three principles of respect for persons, beneficence, and justice were identified as guidelines for responsible research using human subjects in the Belmont Report (1979). Thus, in both clinical medicine and in scientific research it is generally held that these principles can be applied, even in unique circumstances, to provide guidance in discovering our moral duties within that situation.

Four commonly accepted principles of health care ethics, excerpted from Beauchamp and Childress (2008), include the: Principle of respect for autonomy, Principle of nonmaleficence, Principle of beneficence, and Principle of justice. Collectively these four have been termed as 'principilism'.

1. Respect for Autonomy

Any notion of moral decision-making assumes that rational agents are involved in making informed and voluntary decisions. In health care decisions, our respect for the autonomy of the patient would, in common parlance, imply that the patient has the capacity to act intentionally, with understanding, and without controlling influences that would mitigate against a free and voluntary act. This principle is the basis for the practice of "informed consent" in the physician/patient transaction regarding health care.[3]

2. The Principle of Nonmaleficence

The principle of nonmaleficence requires of us that we not intentionally creating a harm or injury to the patient, either through acts of commission or omission. In common language, we consider it negligent if one imposes a careless or unreasonable risk of harm upon another. Providing a proper standard of care that avoids or minimizes the risk of harm is supported not only by our commonly held moral convictions, but by the laws of society as well. This principle affirms the need for medical competence. It is clear that medical mistakes may occur; however, this principle articulates a fundamental commitment on the part of health care professionals to protect their patients from harm.[3]

3. The Principle of Beneficence

The ordinary meaning of this principle is that health care providers have a duty to be of a benefit to the patient, as well as to take positive steps to prevent and to remove harm from the patient. These duties are viewed as rational and self-evident and are widely accepted as the proper goals of medicine. This principle is at the very heart of health care implying that a suffering supplicant (the patient) can enter into a relationship with one whom society has licensed as competent to provide medical care, trusting that the physician's chief objective is to help. The goal of providing benefit can be applied both to individual patients, and to the good of society as a whole. For example, the good health of a particular patient is an appropriate goal of medicine, and the prevention of disease through research and the employment of vaccines is the same goal expanded to the population at large.[3]

4. The Principle of Justice

Justice in health care is usually defined as a form of fairness, or as Aristotle once said, "giving to each that which is his due." This implies the fair distribution of goods in society and requires that we look at the role of entitlement. The question of distributive justice also seems to hinge on the fact that some goods and services are in short supply, there is not enough to go around, thus some fair means of allocating scarce resources must be determined. It is generally held that persons who are equals should qualify for equal treatment. This is borne out in the application of Medicare, which is available to all persons over the age of 65 years. This category of persons is equal with respect to this one factor, their age, but the criteria chosen says nothing about need or other noteworthy factors about the persons in this category. In fact, our society uses a variety of factors as criteria for distributive justice, including the following:

To each person an equal share

To each person according to need

To each person according to effort

To each person according to contribution

To each person according to merit

To each person according to free-market exchanges (2).

The present paper deals with the Principle of Autonomy, its implications on informed consent and patient care situations.

The Principle of Autonomy

The term, ''autonomy'' is a word of Greek origins, as it comes from the Greek word ''eautos'', which means self, in combination with the word ''nomos'', which means rule, governance or law. The term

''autonomy'' is used in the English language for describing a person's capacity to express freely his/her will, or his/her capacity and freedom for action in a particular society. Nevertheless, the term autonomy has a complexity in its nature and therefore various attempts to define the term have been made.[4]

In the middle '80s Gillon (1985) argued that the concept of autonomy incorporates the exercise of what Aristotle called man's specific attribute, rationality.[5]

More recently, Osman and Perlin (1994) defined autonomy as the deliberate choice making.[6] Smith (1994) described a broader definition which refers to autonomy as "a set of diverse notions including self-governance, liberty rights, privacy, individual choice, liberty to follow one's will, causing one's own behavior and being one's own person".[7]

In 1994, an editorial in the journal Lancet, related to patients' rights and autonomy, stressed that people are being granted self-determination and the right to govern themselves, including the right to determine their own health priorities.[8,9]

Some years later Nessa and Malterud (1998) described autonomy as a sort of mental competence that determines both the individual's inner and outward behavior.[10]

In the new millennium, Leino-Kilpi et al. (2000) argued that there are three central concepts of autonomy: 1. Self-governance, 2. Self-realisation and 3. Actual autonomy and defined autonomy as the ability to think decide and act according to that thinking and decision.[4] In 2002, Vaughan and Leddy supported similar ideas that describe autonomy in the personal sense as the personal freedom, the freedom of will and the right of self-government.[11]

THE PATIENT'S RIGHTS

The Universal Declaration of Human Rights (1948), stated that: "everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and services".[12] The first country in the world with a special law regarding patients' rights was Finland, where a law on the patient's status and rights came into effect in 1992.[13]

The World Health Organisation is dedicated providing strong, international leadership for promoting, advancing and protecting the right for health as a fundamental human right.[14] The first international event with a focus on the topic of patient's rights was the European Consultation on the Rights of Patients meeting with the support of W.H.O. Regional Office for Europe, in 1994. The event was hosted by the government of the Netherlands and the resulting Consultation document formulated for the first time in the history the principles of Patients' Rights.[13] The declaration which was unanimously, accepted by the 36 participating countries, includes specific elements concerning respect of the human rights and values in health care, information about health services and for the best use of them, consent, confidentiality and privacy, care and treatment.[9,13]

Patient's autonomy

Respect for patient autonomy has been defined as the core legal and ethical principle that underlies all human interactions in health care. Every adult human being of sound mind has a right to determine what shall be done with his own body and he/she has the right and responsibility to make health care decisions.[15] The autonomous person can act, choose and think as he/she wishes.[4] However, it has to be stressed that individuals have the right to determine the course of their life as far as there are no restrictions to the autonomy of others.

Autonomy means that people have the right to make their own decisions as far as their decisions do not interfere to others.[4] Consequently patient's autonomy includes the rights of individuals to make informed decisions about their medical care.[16] and that implies a right to set limits for medical intervention.[10]

At this point another issue arises regarding the health professionals' duties. As Leino Kilpi et al., (2000) argue, for the protection of patients' autonomy, health professionals should always try to ensure that people are not treated against their will that they are informed about their treatment and care and that they are involved in the decision-making process regarding that care.[4]

Since the autonomy concept is complex, various authors have tried to analyze patient autonomy, by considering its individual components.

For example, Bayne (1998), approached the principle of autonomy by presupposing two ideas: a) the

recognition of the fundamental value of an individual's free choice for their life, plans and their personal adaptation to the ideals of human excellence, and b) the state and other individuals must not interfere in these choices.[17]

After reviewing the health care literature related to patients' autonomy Dowrkin (1998) identified two features that are common to almost all the definitions of autonomy. 1. Autonomy relates to individuals, and 2. Autonomy is a desirable attribute.[18]

Leino-Kilpi et al (2000) distinguished patient's autonomy into three levels: 1) Autonomy at the physiological level involves an autonomous process and it is characterized by its independence from other autonomous processes. 2) Autonomy at the personal level involves the determining and defining of the self. It suggests a liberty to act in accordance with one's will, having independent thought and control over choice, and 3) Autonomy at the social level, which suggests that a model of autonomy should take constraining factors into account.[4]

Ikonomidis and Singer (1999) stressed that concern for autonomy stems from individuals' interest in making significant decisions about their lives according to their own values or concept of a good life.[19]

Barer, (1997) supported that the respect for patient's autonomy presupposes that patients should be informed about possible alternative treatments.[20s] while Haddad and Vernarec, (2001) argue that health care professionals should ensure the respecting of patient's autonomy by sharing their personal experience and allowing patients to decide whether or not they want to hear it.[21]

Despite the developed literature and efforts made, patients are very often excluded from the health care decision process and usually health care professionals come first to an agreement regarding treatment or care and then they discuss it with the patient.[17].

However, patients and health care professionals should have as their common goal the realization and maintenance of the patients' capacity to be free and autonomous. Therefore, health care professionals should make sure that patients understand the basics of their diagnosis and their proposed treatment and they have to help them feeling secure to refuse professional suggestions if they wish to.[10]

Nevertheless, there are some occasions when the physician may determine that a patient's decision making capacity is impaired. Then, a surrogate should be involved in decision making who will follow the directions, values, preferences of the patient in an effort to make a decision as the patient would have done.[22] In addition, another important point it is stressed in the health care literature, the cultural issue because as Leino-Kilpi et al. (2000) argue that the concept of autonomy has different meanings in different cultures.[4]

The concept of informed consent

Every person has the right to receive information about the availability of health services, about one's own condition and about applicable treatment, including information about the health care providers.[4]

Patients have the right to be involved in all aspects of their care, including giving informed consent to the health care provider.[23] Informed consent is grounded in the ethical principle of respect for persons as autonomous and it is the cornerstone of patient autonomy.[24] Autonomous persons are capable of deliberation concerning personal goals and of acting under this direction of deliberation.[25] The concept of informed consent in biomedical ethics means a voluntary uncoerced decision, which is made by a competent autonomous individual to accept or reject some proposed course of action.[26]

The ethical imperative of giving patients comprehensive information allows the patients to make independence choices. During this process explicit communication of information is provided that would relevant to help the patient decide whether or not to have a particular treatment or procedure.[4] The informed consent process should be seen as an opportunity for the patient to be an informed participant in his/her health care decisions and as an invitation for participation to health care decisions.[27,28] As far as patients have the right to obtain information about their health care, they have also the right to accept or reject any suggested options.[29] This is a fundamental right of the patient and therefore, only after obtaining patient's consent treatment can be started and/or continued.[30, 31]

Informed consent is a process, which guarantees the patient's freedom, privacy and safety[35] and one of its purposes it is to maintain trust between health

care professionals and patients.[28] The health care professional who will perform a procedure is responsible for obtaining the patient's consent.[33]

However, to arrive at informed consent, it is necessary to provide the patient with adequate information about all aspects of his/her choices and this information should be sufficient and accurate.[21] Adequate information includes explanation and details on the benefits and risks of the proposed and alternative treatments. They also should include the option and consequences of no treatment.[4,34,35] The information provider should be sure of the mental competence of the patient in order to affectively transmit information which effect informed choice.[33,36]

Health care professionals and patients should actively participate in the informative process in order to execute informed consent.[37] The provided information should be in a way, which does not increase anxiety or decrease confidence. The information should be clear and simple, avoiding medical terminology and technical expressions. Patients should be encouraged to ask questions and their understanding should be checked.[38] The presentation and explanation of the information should be adjusted to suit the patient's language, level of maturity and competence. The patient should be able to weigh the relevant factors in order to conclude to a balance view and finally make a decision.[36] The information should be provided far in advance in order for the patient sufficient time to give it due consideration and arrive at a decision voluntarily.[4,33]

A variety of ways can be used in order to provide information to the patient and better quality of informed consent could be obtained by combining oral and written information.[32,39]

Nevertheless, there are individuals, who report difficulties in obtaining relevant information. Pfeffer and Alderson (1997) identified three vulnerable groups in the process of obtaining the informed consent. These are: 1) children, 2) patients with learning difficulties and 3) unconscious or semiconscious patients.[40]

Sometimes, health professionals underestimate the patients' desire and ability to cope with such information. Often, the consultation time is limited, and there are even occasions when health professionals lack the knowledge of treatment options and their effects. A solution to this problem could be the use of written or audio-visual material.[41] For example, since 01.01.99, in accordance with the European Union legislation, medicines dispensed in the member countries must be accompanied by printed information.[42]

Furthermore, there is a great deal of evidence that points to the fact that patients who are satisfied with their care are those who have their desires and requests met.[43] In addition, informed patients are more co-operative and they recover more quickly.[44,45] Moreover, patients who are involved in decision making are more ready to follow the instruction of health care professionals.[46]

Nevertheless, there are also contrasting opinions on patients' satisfaction. Although Joos, Hickman and Borders, (1994) found that the majority of the patients showed desires for basic information about disease conditions and medications,[47] most of the literature claims that usually patients wish to be informed but feel detached from the decision making process.[48]

Requirements for informed consent[2]:

1. The patient or surrogate must:

- Be competent, that is, capable of understanding consequences of the consent and capable making a free choice.
- Be free from coercion or undue influence.

2. The health care provider must:

- Provide and make understandable necessary information for making a free, intelligent treatment decision and must make sure that the patient or surrogate understands the information.
- The only way to know if the patient understands the information is through reflective conversation with the health care provider.
- The health care provider must recommend what he or she takes to be the optimal option and is free to persuade, without pressuring, the patient of this option.
- Note that legal informed consent, e.g. signing a waiver, does not meet the moral standards of informed consent.

Requirement of a person to be competent:

- One must presume that adult patients are competent.
- Competence to make medical decisions requires that the patient know that he or she is authorizing medical treatment and is able to understand effects of treatment, options in terms of health, life, lifestyle, religious beliefs, values, family friends, and all other factors bearing on treatment decision.
- There is no easy way to determine incompetence except through the requirement that the health care provider spend time getting to know the patient and the patient's mind and understanding.
- Factors to consider: inability to express preference, inability to understand one's situation and its consequences, inability to understand relevant information, inability to give a reason, inability to give a rational reason, inability to give risk/benefit reasons, inability to reach a reasonable decision.
- The relevant competence is competence to make the specific treatment decision at hand.
- The fact that the patient has values different from the health care provider does not by itself prove the patient incompetent.
- Standards for competence may be set higher in cases where the consequences are more substantial.

What should one do in case a patient is incompetent?

- First, the medical practitioner must consult the patient's living will if there is one.
- Second, if there is no living will or the living will provides no clear guidance, the medical practitioner must consult a surrogate decision maker: either one designated by a durable power of attorney, or a family member, in order of priority: healthcare durable power of attorney, or guardian; spouse; children of legal age; parents; siblings of legal age; grandparents; grandchildren of legal age; other relative, close friend, or caregiver.

Disclosure required in order satisfying the demand for informed consent:

There are two different possible standards for full disclosure:

A. The prudent person rule

B. The subjective substantial disclosure rule

The prudent person rule requires that the patient knows and understands:

1. The diagnosis
2. The nature and purpose of the proposed treatment.
3. The known risks and consequences of the proposed treatment, excluding those too remote and improbable or too well known to bear on the treatment decision.
4. Included should be the doctor's and hospital's success and failure rates with the proposed treatment and "judgment errors made in the course of care if such information affects the care of the patient"
5. The benefits expected of the proposed treatment and the likelihood of their being realized.
6. All alternative treatments, with all the information for them mentioned in 3 and 4 above.
7. The prognosis if no treatment is given.
8. All costs and burdens of the treatment and of the alternatives mentioned in 5 above.

The subjective substantial disclosure rule requires that the health care provider describe to the patient everything material or important to that particular patient, that is, all information that could alter the patient's reasoning about the treatment, given his or her principles, beliefs, and values. Note that this rule invalidates any blanket disclosure policy. For example, a blanket disclosure policy of not informing patients of improbable risks violates, or may violate this rule. Note also that the parallel requirement of informed consent in medical research demands that "no fact should be concealed that might cause the particular patient, or a reasonably prudent person, to refuse participation in the study".

Exceptions to the requirement to seek explicit informed consent

A. Implied consent- When consent is implied and procedures are not risky or invasive.

B. Therapeutic privilege- If there is a reason to believe that information given to a specific patient will results in an adverse effect on the patient's condition or health, information may be withheld. (See AMA Code, 8.08 and American College of Physicians Ethics Manual, 8) But note that studies show that health care providers misestimate their patents adverse responses. So, therapeutic privilege is almost never justified.

C. Emergencies- If the patient is not competent and no surrogate is available and his or her advance wishes are not known and there is danger to life or danger of serious impairment to health, and immediate treatment is necessary to avert these dangers, then the obligation to seek informed consent is waived.

D. In a case in which the patient's capacity to reason and sense of values may be affected by his or her illness or some transitory mood and treatment would bring about an irreversible state, the health care provider may be justified in postponing treatment even if the patient wants it, based on an appeal to beneficence.

Informed consent & patient autonomy

An informed consent in the health service is an autonomous person's authorization of health personnel's professional actions towards the person.[49] Consequently, the consent is a statement that persons with a given profession can act in ways that would otherwise not be allowed (for example, cutting them). A general requirement for consent from the patient entails that he / she as a rule may refuse any kind of health care. The informed consent can therefore prevent the patient from receiving undesired health care, including health care that health professionals believe is indicated. This does not mean that patients or their families should be able to order health giving inappropriate or purposeless health care.[50-52]

An influential reason for the consent is that it is a moral act in line with the principle of autonomy, which can be said to be a part of our general morality,[2] or can be justified by the individual's freedom to follow his own goals.[53] Autonomy, and the importance of respecting autonomy can also be rooted in the human ability to be "self-regulatory"[54,55] or to subordinate immediate preferences under more long-term preferences.[56] The consent in the health service is also often produced as a concretization of more general rights.

The importance of the informed consent can also be said to be linked to ideological conditions, such as individualism and consumer mentality.[55] Regardless of the theoretical and ideological background, there seems to be a fair consensus on the three mentioned prerequisites for autonomy and consent: Understanding, Consent and Volunteering.

Understanding

A prerequisite for the patient to understand an action option is that the patient has received enough information, for example about his / her own state of health, possible causes and prognosis, content and effects as well as side effects of health care. An important and difficult question is what requirements should be made for the patient to get enough information. According to section 3 - 5 of the Patients' Rights Act, the information must be adapted to the individual's premises, given in a considerate manner, and the healthcare staff shall as far as possible ensure that the patient has understood the importance of the information.

In practice, it is often difficult to know if the patient has understood the content and importance of the information. A survey of the types of issues discussed in a clinical ethics committee in Norway showed that ethical challenges related to information and communication occurred frequently.[57] The cases illustrated communication failure related to what was said, timing and the manner in which the information was conveyed, and it was warned against underestimating the complexity of medical information. The provider of information may also face an ethical dilemma between reducing patient autonomy by keeping back information or inflicting patient suffering through providing unwanted information. Another challenge is that the information can be interpreted differently. An important example is information about risk.

UNDERSTANDING OF RISK

Epidemiological risk is generally challenging to relate to individuals.[58] Moreover, the perception of perception of the physicians and experts seems to be different, and health personnel's understanding

of risk may also vary. Risks communicated in mathematical terms often seem unlikely in the face of laymen. Healthcare professionals should also take into account that patient perception of risk may be subjective and simplified. The likelihood of rare and dramatic causes of death appears to be overestimated while more common causes of death are underestimated.[59] Many also look at and perceive risk phenomena in a categorical manner, either dangerous or safe.[59] A qualitative study of patients' perception of informed consent in the acute phase of acute myocardial infarction indicated that bleeding risk was insufficiently perceived.[60] There is also a great risk that risk information will be colored by the recipient depending on how it is presented. Positive versus negative formulations, such as risk of dying versus chance of survival are examples of this. The same applies to the relationship between numerical information versus adjective, such as "rare" or the like.[61]

TRUST

Confidence is particularly important and skirted in asymmetric relationships, for example, in the physician-patient relationship, where there is often a significant potential for abuse of power. Also in situations where there is some degree of uncertainty, ignorance or anxiety, for example when a seriously ill patient is admitted to a modern hospital for complicated treatment, trust is central[55] Trusting a doctor does not just mean that we trust the doctor is professional, but we also like to trust that the doctor will take a certain care of our interests, even if unforeseen situations occur and not all is explicitly agreed upon advance. If doctors limit their responsibility to make the patient request without considering what is best for the patient, it can cause patients to become insecure or lose faith in the leg's integrity. Some have pointed out that autonomy understood as individual independence, independence, or the individual's free choice, is an unrealistic and misleading ideal in meeting with vulnerable, suffering or addicted patients.[55]

Some patients have high confidence in the doctor's assessments and want the doctor to make the decision on their behalf. That patients want a lot of information does not necessarily mean they want to participate in treatment decisions. A literature study of patient preferences for participation in clinical decisions found that the majority of respondents wanted to be informed of their illness, while there was significant variation in the desire to participate in medical decisions.[62] Another study aimed at patients with hypertension found that the need for information and discussion about the treatment was underestimated by the doctors while the patients' need for involvement in treatment decisions was overestimated. Almost half of the informants preferred that the doctor made the therapeutic decisions. It was recommended that clinicians explicitly investigate what the individual patient prefers from information and participation in clinical decisions.[63]

CONSENT EXPERTISE

There are several different tests and tutors to assess consent competence, such as developed through empirical research, ethical reflection and case law.[64-66] The tests usually focus on the following four areas:

- the ability to express a choice
- the ability to understand information relevant to the decision on health care
- the ability to recognize this information in its own situation, especially in relation to its own disorder and the possible consequences of the various treatment options
- the ability to reason with relevant information in a weighing of the different treatment options

Assessing the competence of consent, however, also requires basic knowledge of the principle of respect for patient autonomy and informed consent, in addition to knowledge of the patient's clinical condition and the requirements for the current decision to be taken (64). Knowledge of the patient's clinical condition will not be enough to assess whether the patient is competent for consent, albeit with certain exceptions (e.g. comatose patients, highly psychotic or very demented patients). That the patient has been given sufficient information and that the decision is taken without compulsion, as indicated above, is not part of the assessment of consent itself, but the prerequisites for a valid consent, in addition to the consent of the patient. There are many common misconceptions associated with patient consent, for example, "patients who do not follow the advice of the doctor, have reduced consent", "patients who are compulsive or demented, lack consent power", "when consent is lacking, it is lacking in all decisions" , "Lack of consent competence is permanent".[67]

According to section 4 - 3 of the Patients' Rights Act, it is the person who provides the health care which determines whether the patient has the consent of the patient, and it is apparent from the preparatory work of the Act that this means the person who has the professional responsibility for the treatment.[68] Doctors thus have a central position in this type of assessment, and health legislation gives health personnel relatively large definitions of what it means to be consented to consent. However, it should be investigated whether the assessment of consent competence is adequately emphasized in the primary and further education of doctors and other healthcare professionals and how assessments of consent competence take place in the health service.

Volunteerism

The third criterion of autonomy and consent is voluntary. An act is not autonomous if actions are performed under compulsion, even if the person is in agreement and understands relevant information. For example, patients may be under pressure from the family or from healthcare professionals. The patient's volunteering may also be undermined by the angulation of the information provided or strong recommendations. Most people agree that coercion for compulsive persons is wrong and that it is impossible to be completely neutral to the patient. However, there is a great deal of disagreement about how far one can go in persuading patients and whether manipulation in some cases may be legitimate.[69] It is legitimate to try to convince a patient that a given action is the best option through an open dialogue, including The doctor explains his point of view, the patient receives honest answers to his questions and concerns, and together he tries to find the best solution. On the other hand, it is illegitimate with persuasion or rhetorical manipulation, for example through strategic use of information, abuse of authority or by giving patient needs insufficient space in the conversation. However, it is often difficult to make sure that you move on the right or wrong side of this distinction.

DISCUSSION

In this paper, an overview concerning patient's rights of autonomy and informed consent is made, based on a review of the existing literature.

Autonomy is a complicated concept involving philosophical, humanistic, personal and social aspects. With respect to patient, autonomy has been characterized as the core legal and ethical principle underlying all human interactions in health care. However, individuals understand autonomy in their personal way which reflects the perception of the concept as it is distilled from the individual mixture of experiences, values, ethics, stereotypes and other cultural factors. Although respect for patient autonomy represents a fundamental ethical principle in health care, patient autonomy is an interdisciplinary enterprise and the variety of professional views produced a variety of definitions.

Another essential right of patient is informed consent. Every individual has the right to receive information about the availability of health services, about one's own condition and about relevant treatment strategies. Informed consent is grounded in the ethical principle of respect for persons as autonomous beings and it is the cornerstone of patient autonomy. The concepts of autonomy and informed consent are different, but they overlap in areas of definition as well.

Health care professionals should always consider the client's rights as important factors intervening in the provision of high quality care. Moreover, health care professionals, having knowledge and respect of patient's rights are able to improve the ethical quality of care and fulfill their aim of promoting and supporting the health of their clients.

Furthermore, continuing educational programs for the existing health care staff, emphasizing patients' autonomy and informed consent, may have an impact on their practices as well.

CONCLUSION

Informed consent and autonomy have a central place in legislation and in people's awareness and have gained importance in clinical practice. Healthcare staff has important tasks such as providing adequate information, ensuring that the information is understood, assessing whether the patient is in agreement and taking care of the ideal of volunteering. Adapting the decision-making processes to the patient's assumptions and wishes and assessing the patient's consent competence are some of the most important ethical challenges the health services face.

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