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Clinical audit of ectopic pregnancy

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Abstract

Objective: The aim of this study was to determine the risk factors of ectopic pregnancy in cases presented to the Woman's Health Hospital (WHH) in Assuit University, and to perform clinical audit on strategies for management of ectopic pregnancy in the WHH.

Methods: This descriptive hospital based study was conducted at the Woman`s Health Hospital (WHH) of Assuit University (Egypt). There were 210 patients who were admitted to the WHH with the diagnosis of ectopic pregnancy in the period between February 1, 2015 through the end of October 2015. Data were analyzed by SPSS version 21, using descriptive statistics, Mann-Whitney U test, and Chi square.

Results: Ectopic pregnancy affects woman in the reproductive age. There are many risk factors that increase the chance of its occurrence; however, it may also occur in the absence of any risk factors (14.0%). Internal VD (72.5%) is the most frequent risk factor; other risk factors include history of abortion, previous CS, ovulation induction, history of infertility, or previous history of EP.

Conclusion: Clinical audit is an important item of any adequate health care. As regards to the clinical audit of EP management, we are not adhering to the guidelines.

Keywords: Clinical audit, Ectopic pregnancy, Risk factor, Egypt, Assuit

1. Introduction

An ectopic pregnancy (EP) occurs when a fertilized ovum implants outside the normal uterine cavity (1). In industrialized countries, up to 2.0 % of all pregnancies are ectopic in location (2), and now it is also a growing problem in developing countries (3). Approximately 75.0 % of deaths in the first trimester and 9.0 % of all pregnancy-related deaths are due to EP (4). Almost all EPs occur in the fallopian tube (98.0%) (5), the ampulla is the most common site of implantation (80.0%), followed by the isthmus (12.0%), fimbria (5.0%), cornua (2.0%), and interstitia (2.0-3.0%) (6). The etiology of EP remains uncertain although a number of risk factors have been identified (7). A common factor for the development of such ectopics is the presence of a pathologic fallopian tube (8). EP may be asymptomatic, and the most common clinical presentation is first trimester vaginal bleeding and/or abdominal pain (9). Its diagnosis can be difficult. In current practice, in developed countries, diagnosis relies on a combination of ultrasound scanning and serial serum beta-human chorionic gonadotropin (β-hCG) measurements (10). EP is one of the few medical conditions that can be managed expectantly, medically or surgically (11). Surgical methods are still the mainstay in the management of EP, and in developed societies, laparoscopic surgery is currently the gold standard. Audit in healthcare is a process used by health professionals to assess, evaluate and improve care of patients in a systematic way. Audit measures current practice against a defined (desired) standard. It forms part of clinical governance, which aims to safeguard a high quality of clinical care for patients (12). The objectives of this research were set as the following: 1) Determining risk factors of ectopic pregnancy in cases

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presented to the Woman's Health Hospital (WHH) of Assuit University, 2) Clinical audit on strategies for management of ectopic pregnancy in the WHH.

2. Material and Methods

2.1. Study setting

This hospital based study was conducted at the Woman`s Health Hospital (WHH), Assuit University. Study population were all women (210 patients) admitted to the WHH with the diagnosis of ectopic pregnancy in the period between February 1, 2015 through the end of October 2015. Data were collected directly from patients, relatives, and case records in a specially designed data collection sheet.

2.2. Selection criteria

Inclusion Criteria were all women diagnosed as ectopic pregnancies who were managed in the WHH during the study period. Exclusion criteria were 1) Heterotopic pregnancies, and 2) Patients who did not wish to be treated at the WHH.

2.3. Data collection

The current study included two main parts: The first part evaluated the risk factors of ectopic pregnancy. The evaluation was done using a data collection sheet. The second part of the study included a clinical audit on the management of ectopic pregnancy at the WHH, conducted in these steps: 1) Choosing ectopic pregnancy as audit; 2) Agreeing standards of best practice (audit criteria), obtained from the Royal College of Obstetricians and Gynecologists NICE clinical guideline 154 (December 2012); 3) Collecting data: using a specially designed data collection sheet prepared by the investigators using the items obtained from the above guideline; 4) Analyzing the obtained data against the prepared checklist; 5) Feeding back results and discussing the possible points needed to be addressed; and 6) Action plan to implement the agreed required changes. All patients were subjected to a full history taking and physical examination and laboratory test including complete blood count, urine pregnancy test, qualitative or quantitative serum β-hCG, ultrasonography and whether it was abdominal or vaginal with determination of the size of the adnexal mass if present, and the presence of intraperitoneal fluid and its amount and laparoscopy if done.

2.4. Ethical considerations

The study protocol obtained ethical approval from the ethical committee in the Faculty of Medicine in Assuit University. Regarding the risk-benefit assessment, there were no risks affecting the patients in this study. Regarding confidentiality, any data taken from the patient either from the history, the examination or from the investigations, were dealt with in a confidential manner.

2.5. Statistical analysis

Data were analyzed by IBM© SPSS© Statistics version 21 (IBM© Corp., Armonk, NY, USA). Data were expressed as mean, standard deviation, number, and percentages. Mann-Whitney U test was used to determine significance for numeric variable. Chi Square was used to determine significance for categorical variable. $P < 0.05$ was considered significant.

3. Results

3.1. General findings

There were 210 cases of ectopic pregnancy, of which, 10 met the exclusion criteria and therefore, did not enter the study. Also, the following are descriptions of the study subjects:

1) Undisturbed: n =28 (14.0%), 4 expectant management, 16 medical treatment (one cervical ectopic failed medical followed by evacuation), 5 Laparoscopies: (4 salpingectomies and 1 salpingostomy) and 3 Laparotomies (all salpingectomy).
2) Chronic disturbed: n=14 (7.0%), 1 expectant management, 4 medical treatments (one failed followed by laparoscopy), 3 Laparoscopies (One after failed medical treatment), 7 Laparotomies (5 salpingectomies, 1 salpingostomy, 1 milking).
3) Acute disturbed n=158 (79.0%) All are treated by laparotomy (one after failed laparoscopy).

Regarding the demographic data of the study participants, their mean age was 27.30 years (±5.80), ranging from 18 to 44 years old. . Of the 200 patients, 182 (91%) were residents of rural areas and 18 (9%) were residents of urban areas. Regarding the reproductive history of the study participants, 77.5% of them had regular menses and the mean

number of days from the last menstrual period was 41.01±21.27 days. The mean parity of the study participants was 1.91±1.64. Most of the patients were multipara (65.0%). The mean number of previous abortions was 1.62±0.68. Most of our patients (97.5%) had lower abdominal pain, 75.5% of patients had missed period, and 54% had vaginal bleeding. The sites of lower abdominal pain were right (34%), left (28.5%), and bilateral (37.5%). Thirty-seven patients (18.5%) had pregnancy symptoms and 19.5% had history of syncope attack(s).

3.2. Evaluation of the risk factors of ectopic pregnancy in Assuit setting

The other risk factors were: using drugs for ovulation induction (19.6%), previous history dilatation & curettage (18.5%), history of infertility (17%), past history of abdominal or pelvic surgery (16%), using contraceptive pills in the last 6 months (11.5%), using an intrauterine contraceptive device (IUD) in the last 6 months (6.5%), history of ectopic pregnancy (5%), current IUD user (4.5%), assisted reproductive technology (3%), history of documented pelvic inflammatory disease (PID) (1%), documented tubal pathology (1%), and smoking (1%). Also, there were no patients with history of documented endometriosis; and 14% of the patients had none of the above risk factors. More than half of the participants (62.8%) were using vaginal douching (VD) once or twice per day. The majority of our participants (97.94%) were using their fingers for introducing water with or without detergents into the vagina. Most of them (69%) were using tap water for VD.

3.3. Auditing (the management of ectopic pregnancy versus the NICE guideline 154-2012)

In this part of the study we are presenting the results of clinical audit on the performance of the WHH in the management of ectopic pregnancy. First, regarding the examination of the study participants, the presence of pallor was only performed in 25.0% of cases and none of the examiners measured the respiratory rate or temperature. The rate of performance of the rest of vital data was summarized in Table 1. Table 2 addresses the revising of investigations done to the study participants as compared to what is recommended in the NICE guidelines. With a urine pregnancy test the U/S (abdominal or vaginal) was done in 100.0% of cases and U/S was performed by experienced staff in all cases (100.0%). Regarding serum β-hCG, it was done only in 35.5% of cases. Comparing the lines of management of ectopic pregnancy at the WHH with the clinical guidelines (NICE 154) shows that only one case of eligible cases of acute disturbed ectopic pregnancy (29) was done laparoscopically while the rest were done using laparotomy.

Table 1. Auditing of the examination of cases of ectopic pregnancy in WHH

Variable	Study group (n=200)	NICE clinical guideline	p-value
Comment on pallor	50 (25.0%)	100.0%	<0.001
Blood pressure P	200 (100.0%)	100.0%	--
Pulse	200 (100.0%)	100.0%	--
Respiratory rate	0.0	100.0%	<0.001
Temperature	2 (1.0%)	100.0%	<0.001
Abdominal examination	200 (100.0%)	100.0%	--
Vaginal examination:	197 (98.50%)	100.0%	0.482

Table 2. Comparing the investigations for ectopic pregnancy to the NICE guidelines

Item	Study group (n=200)	NICE Clinical guideline	p-value
Urine pregnancy test	200 (100.0%)	100.0%	-----
Serum β-hCG	71 (35.5%)	100.0%	0.01*
Repeated s. β-hCG after 48 hrs.	29/32* (90.6%)	100.0%	0.425
Hemoglobin	176 (88.0%)	100.0%	0.375
Ultrasound	200 (100.0%)	100.0%	----
Done by experienced staff	200 (100.0%)	100.0%	----

* Patients who stayed in the hospital more than 48 hours before management

The lower use of laparoscopy is mostly due to lack of 24 hours' availability of a laparoscopy room in addition to lack of training of the young staff on laparoscopic treatment of EP (Table 3). Regarding the follow up of cases of EP managed medically, our findings showed that 80% of patients who received medical treatment had repeated β-hCG on days 4 and 7, and all patients had been counseled for the follow-up after the medical treatment. Regarding the auditing of the operative reported data of cases of EP at the WHH, our residents had reported the type of ectopic pregnancy in 74.0%, and reported the site and side of ectopic pregnancy in all cases. However, the comment on the

other tube and IP blood collection were reported in 86.0 % and 68.0%, respectively. Regarding the mean period of hospital admission in our study participants, the mean period of hospital admission in different lines of management with the longest period for the medical treatment was 7.3 days. None of our study participants had been readmitted to the hospital or died as a result of ectopic pregnancy or its management.

Table 3. Auditing the lines of management of ectopic pregnancy in WHH

Items	Eligible/Actual	Expectant management	Medical treatment	Laparoscopy	Laparotomy
Acute disturbed, n =158	Eligible*	0	0	29	129
	Actual	0	0	1 1	58
p<0.001*		----	----		0.03*
Chronic disturbed n =14	Eligible	1	4	8	2
	Actual	1	4	3	7
p-value		----	----	0.001*	0.02*
Undisturbed n =28	Eligible	4	17	6	1
	Actual	4	16	5	3
p-value		----	0.275	0.329	0.242
Total 9 (4.5%)		5 (2.5%)	20 (10.0%)		168 (84.0%)

* Eligible: means that the NICE recommendations point to this line of management

4. Discussion

Three quarters of the women presented with EP were performing the practice of internal VD. This agrees with a study on the same setting (13) which reported that 73.0% of women with vaginal infections were performing this practice. Regarding the management strategy of 200 cases of EP, 84.0% of cases were managed by laparotomy, while 4.5% of cases were managed by laparoscopy, 10.0% with medical treatment and 2.5% had had expectant management of EP. This is in accord with some studies in which the result was near to our result (14). On the other hand, there was a recent retrospective audit study in the UK, in which non-surgical management (expectant and medical treatment) was used in 31% of patients and surgical management was used in 69% of patients. (From the surgically managed group 99% were planned for laparoscopy and 1% for laparotomy, 2% of the laparoscopic group was converted to laparotomy) (15). Clinical audit is an important item of any adequate health care. As regards to the clinical audit of EP management, we are not adhering to the guidelines.

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Conflict of Interest:
There is no conflict of interest to be declared.

Authors' contributions:
All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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