The diagnosis and management of ectopic pregnancy presenting to Mater Dei Hospital between June 2019 and June 2020

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ABSTRACT

The incidence of ectopic pregnancies has steadily increased over recent years and despite advances in treatment it still remains a major cause of maternal morbidity and mortality. The objective of this audit was to assess whether diagnosis and management is occurring as per international suggested guidance and practice. This study is a retrospective one using data collected from June 2019 to June 2020. All data were password protected and kept anonymous. No patient contact occurred. The standard cross referenced was the ‘April 2019 NICE Guideline on the Management of Ectopic Pregnancy’. Thirty-one ectopic pregnancies occurred between June 2019 and June 2020. Twenty-nine underwent surgical management and two medical. Six out of the 29 surgically managed patients were managed incorrectly. Twenty-four of the surgical cases were managed laparoscopically. Presence of a foetal heart rate remained undocumented in 21 out of 31 of cases. The results highlight the ease of access to emergency gynaecological services at Malta’s national hospital. However, this audit did highlight the discrepancy that can occur in examination in association with ectopic pregnancy. An inconsistency was noted in documentation. Additionally, a number of cases could have been offered and benefitted from different modes of management.

IMPACT STATEMENT

What is already known on this subject? Ectopic pregnancy (EP) is an important cause of morbidity and mortality in mothers of childbearing age. The diagnostic method and appropriate management for EP has been extensively studied. Concrete- and evidence-based guidelines guide clinical management and improve morbidity and mortality. Local guidelines improve clinical outcome.

What do the results of this study add? This study shows the impact of clinical outcome without a national guideline to guide management on a national level. Malta has one national hospital in which the local obstetrics and gynaecology department is run. The results of this study thus comprise of nationwide statistics on EP and its management. Ectopic pregnancies are managed without a local guideline in place. It also reflects the ease of access to health care in smaller countries.

What are the implications of these findings for clinical practice and/or further research? The findings of this study have resulted in the production of a local guideline for the management of EP, as well as the introduction of a protocol for obtaining methotrexate for medical management. It has introduced new ultrasound machines and staff training to aid diagnostics. Further re-auditing will be carried out to analyse the impact a local guideline has on clinical practice at a national level.

Introduction

The diagnosis of an ectopic pregnancy (EP) is unexpected and is an emotionally traumatic event. Most women may have only recently discovered they were pregnant when they receive the diagnosis.

An EP is when the zygote implants outside the uterus. This occurs in approximately 1.1/1000 pregnancies. The incidence has remained stable in recent years, although previously it was steadily rising. The previous increase in incidence is attributed to a greater incidence in sexually transmitted diseases.

The most common site of EP is in the fallopian tube in particular the ampulla, where fertilisation occurs. Others may be located in the cervix, ovary or abdominal cavity, but are less frequent.

Worldwide, EP remains the leading cause of maternal death in the first trimester (Autry 2013). In Malta, as in most of the developed world, there has been a reduction in mortality from EP reflecting a success story of modern medicine. Modern management has converted a life-threatening surgical emergency in a woman with a positive pregnancy test and haemodynamic shock to a non-urgent medical condition in many cases. In Europe from 1970 until 1992, the mortality rate decreased by 90% despite a simultaneous sixfold increase in incidence of EP.
The major improvement in mortality came as a result of earlier and more accurate diagnosis, made possible by the development of high-resolution ultrasonography and radioimmunoassay for human chorionic gonadotropin (hCG) and also the widespread availability of laparoscopy (Lipscomb et al. 1998). Assessment Units (EPAU)’s have been introduced in many hospitals to provide specialist assessment.

Despite improvements in prompt diagnosis of this potentially fatal condition, there are avoidable factors in over half of the associated deaths. EP remains responsible for 6% of maternal deaths which mainly occur after an acute initial presentation. Women who present with signs of hypovolemia demand rapid diagnosis and management. In spite of the above about half of those with EP presenting to emergency departments, the diagnosis is missed at first assessment (Centre of Maternal and Child enquiries 2011).

Methods

The audit is a retrospective one, for which data were collected from patient files. Data from June 2019 to June 2020 were used. The list of patients with ectopic pregnancies was taken from the pathology specimen records and the admission records. No patient contact occurred during the audit. Data were collected via google forms and then interpreted using google sheets. Data were kept password protected, to which only the auditors had access to. The data were kept anonymous.

As the Maltese national hospital does not have a guideline for the management of EP, the 2019 NICE guidelines were used as a standard. It is important to highlight that Malta offers emergency and gynaecology services at private hospitals. Data from these hospitals were not included in this study. The RCOG green-top guidelines were also cross-referenced.

Demographic data, symptoms, signs, investigations and final management chosen were recorded. The incidence was recorded. The data were analysed in percentages and presented as bar charts or pie charts when appropriate.

Results

In Malta between June 2019 and June 2020, 31 ectopic pregnancies presented to the Obstetrics and Gynaecology Department at Mater Dei. In 2019, a total of 4439 live births were recorded in Malta, with a 0.69% risk ratio of having an EP (Gatt and Zahra 2020). Twenty-nine of these were managed surgically and two medically, as seen in Figure 1. The commonest age group at presentation was 30–49 years. The Obstetrics and Gynaecology Department in Mater Dei is at an advantage as it offers all types of treatment for an EP; expectant, medical and surgical. Twenty-four of the surgical cases were managed laparoscopically and five with a laparotomy, one of which was an emergency. The majority of cases were managed as surgically conservative as possible, hence via laparoscopy. One of the cases managed with a laparotomy did not warrant surgical management and could have had medical or expectant management. The NICE and RCOG guidelines recommend a laparoscopy first line when choosing the surgical management. A laparotomy should be a last resort (Elson et al. 2016; National Institute for Health and Care Excellence 2019).

The majority at 71% (22 cases) presented with vaginal bleeding. Sixty-five percent (20 cases) complained of abdominal pain. The majority of cases presented to the gynaecology admission room at Mater Dei. Presenting symptoms were recorded consistently in every case. Patients have very easy access to a doctor in Malta. Once seen in the emergency department, they will immediately be directed to the gynaecology emergency room. A specialist can be accessed in less than an hour in Malta.

No one had a past medical history of pelvic inflammatory disease (PID). Sixteen percent (four cases) had a history of infertility and one out of the 31 cases had a history of assisted reproductive treatment. It is well known that PID increases the risk of having an EP (Brunham et al. 2015). Forty-two percent (13 cases) of cases had a history of abdominal operations. This is significant as previous abdominal surgery is a risk factor of having an EP (Shehwar and Zubair 2017).

The majority of remaining symptomatology remained unreported. Breast tenderness was documented in one patient. Forty-five percent (14 cases) had no documentation of GI symptoms. Rectal pressure or pain on defaecation was not reported in any of the cases. Similar results were seen with documentation of signs. Pelvic tenderness was the most common sign at 39% (12 cases) and adnexal tenderness was present in 19% (five cases) of cases. However, despite this 26% (eight cases) and 36% (11 cases) respectively had no documentation of pelvic or adnexal tenderness. Forty-eight percent (15 cases) had no cervical excitation test (CET) on vaginal examination and 11 cases had no documentation of CET. Peritoneal signs were not present in 65% (20 cases) of cases. Abdominal distension, enlarged uterus, shock or collapse and orthostatic hypotension remained largely undocumented. The results show a discrepancy in examination and eliciting signs and symptoms in association with EP as well as an inconsistency in documentation on the gynaecology admission sheets. The importance of detailed documentation is imperative to good continuity of care.

Figure 1. Choice of management.
To attempt diagnosis, 65% (20 cases) of cases had two betaHCG readings at least 48 hours apart. The remaining had more than two betaHCGs and five out of 31 patients had no HCG taken.

Ultrasound documentation noted 94% (29 cases) did not report ‘moving separate to ovary’ and 78% (24 cases) did not report foetal pole present. The presence or absence of a foetal heart remained unreported in 68% (21 cases) of cases as seen in Figure 2, that represents 21 out of the 31 cases. On ultrasound, the majority of adnexal masses measured <35 mm, a total of 26 out of 31 cases. On the contrary, the size of the adnexal mass was reported excellently in every case as seen in Figure 3. In cases where a possible EP was in question, 13 out of the 31 cases did not document the presence of fluid in the pouch of Douglas and seven confirmed the presence on examination. In 13 cases, the ultrasound report had no documentation of the presence of an intra-uterine pregnancy.

Discussion

Both the NICE and RCOG guidelines stress the importance of documentation, skilled ultrasonographers and the availability of a senior clinician for reviews. Necessary improvements in these areas have been highlighted by the results.

It is important to note that according to NICE if the possibility of an EP is being considered and an ultrasound scan has been carried out showing ‘an adnexal mass moving separate to the ovary with an empty gestational sack or a complex inhomogenous adnexal mass moving separate to the ovary’, one needs to take into account the clinical presentation and the betaHCG reading to make a diagnosis. There should be no case where a betaHCG has not been taken. The betaHCG value will allow the clinician to decide whether expectant management is an option, as well as following the progress of foetal growth. BetaHCG is also just as essential for monitoring purposes in medical and surgical management. The only aspect betaHCG should not be used for is to determine the location of the EP. The RCOG guidelines support that betaHCG measurements are useful for planning the management of an ultrasound visualised EP. In the cases where more than two betaHCGs were taken, it is important to justify these tests with a senior doctor, so as not to waste expensive resources.

The NICE guidelines highlight the importance of documenting ‘moving separate to ovary’ and ‘foetal pole present’ when reporting an ultrasound to make a definite diagnosis. The same importance is highlighted in the RCOG guidelines. The presence or absence of a foetal heart is imperative when making a diagnosis according to NICE, as no foetal heart allows for medical and expectant management in certain cases. The discrepancy in reporting resulted in inappropriate management in certain cases. Not the same can be said about documentation of the size of the adnexal mass, as it was reported excellently. A further point one must keep in mind that although the NICE guidelines highlight the importance of documenting the fluid in the pouch of Douglas, the RCOG guidelines highlight that only in 25–58% of ectopic pregnancies fluid in the pouch of Douglas was reported. Additionally, it is also a very common finding in intrauterine pregnancies, which puts the importance for diagnostic purposes into question (Elson et al. 2016). Apart from the above, there were several cases where an ultrasound was missing altogether, which should never be the case. During the study period, the only ultrasound result was the one handwritten placed in the patient file. Once this was lost, there was no backup. This has already been improved, as now all ultrasound results can be found on PACS. Hence, an improvement would be expected when re-auditing. Recently, the department also got new ultrasound machines, aiding diagnosis. This can definitely help in the correct management of an EP and avoid inappropriate care, highlighting the importance of a high standard ultrasound service.

The majority of cases, 29 out of 31, were managed surgically. Seven of the 29 surgical cases were managed incorrectly, four warranted medical management and three expectant management. One of the surgical cases was managed inappropriately with a laparotomy. One out of 31 cases was given medical management when surgical management was indicated. According to NICE, whenever possible...
conservative management should be the first choice of treatment. Malta is advanced in offering all types of treatment. However, there are definite limitations with the availability of methotrexate for medical management. No protocol is currently in place for the pharmacy to release methotrexate for medical management of EP. This results in delayed availability and administration of methotrexate, risking overshooting the timeframe one has to treat medically. It is imperative to have a protocol in place for methotrexate as a treatment for EP to help future management of EP.

The audit consisted of some limitations. Data collection was dependent on information from the patient files. Often papers, as well as results, get lost from patient files without a backup available. Some patients were missed from data collection as the identification cards on the databases were incorrect. This shows how important the proper registration of patients is, both on admission and on discharge. Not all risk factors of EP were included in this audit. Previous EP, history of smoking, tuberculosis and endometriosis are all risk factors of EP (Shehwar and Zubair 2017) which could be included in future audits. The age range that was used for this study was quite wide. It would be beneficial to decrease the ranges to 5 years in future re-auditing.

Conclusions

This audit concludes that the usage of guidelines in the management of EP improves outcomes and provides the safest mode of management. A similar audit was carried out in Egypt at the Womans Health Hospital in Assiut. The authors also compared their local hospital management to the guidelines issued by NICE. The timeline used by Hamid et al. is similar to the one used in this audit. Hamid et al. concluded that 29 cases were eligible for a laparoscopy but only one case received it. This is different from our data as the majority of surgically managed cases were managed laparoscopically. Thirty-five percent of cases had a betaHCG reading when compared to 65% in our cohort (Hamid et al. 2017). Their audit highlights the importance of having a local guideline to follow. Berry et al. assessed the management of EP at a single early pregnancy assessment unit over the span of 5 years. Two hundred and eight patients were included and local hospital guidelines were used. They noted an increase in medical and expectant management following an update in guidelines and more consultant led services (Berry et al. 2016). A tertiary centre retrospective study in Turkey assessed local outcomes when following the up-to-date guidelines. The majority of their patients received medical management and had good clinical outcome. The study concluded the importance of determining the most appropriate treatment option for the patient to achieve better success rates (Kömürçü Karuserci and Sucu 2020). Adequate documentation and staff trained in ultrasound skills are two factors that lead to successful diagnostics. In a study conducted in a district hospital in Gauteng, South Africa, 89.7% of EP cases had an ultrasound, but 44.9% of these cases that received an ultrasound were misdiagnosed. They noted a lack of documentation throughout the spectrum of clinical practice.

Suggestions to improve documentation were made, similarly to this audit and the importance of adequately trained ultrasonographers highlighted (Nzaumvila et al. 2018).

Although the scope of this study was to compare local practice to the NICE guidelines, it must be noted that the RCOG guidelines are also of clinical importance and should be included as a standard when assessing clinical practice after a local guideline has been implemented. They should also be considered when creating the local guideline on EP. The RCOG guidelines allow for a more detailed perspective when managing complicated locations of EP; corneal, cervical, etc. rather than giving a generalised approach.

From a local perspective, several suggestions and improvements can be made. Flowcharts based on the NICE guidance have been developed. These flow charts provide easy and clear access to guidance. They can be disseminated amongst all healthcare professionals. They can be displayed in the acute gynaecology admission room located on level 0 green wards or distributed on the Mater Dei P drive. This guideline is meant to be implemented and used in emergency gynaecological services. Training can be provided to staff through the organisation of day seminars and study groups.

The importance of a good ultrasound emergency service was highlighted throughout the audit. A 24 hour ultrasound service is essential in order to ensure proper diagnosis. Both equipment and staff are essential. Staff has over the past three years been trained and accredited as per international guidance in gynaecological and obstetric ultrasound scanning. The department has recently invested in new modern ultrasound machines; these have increased both diagnostic potential and improved reassurance whilst scanning.

Documentation is an essential component of data management. Proper documentation improves outcomes. Documentation is of the highest importance to allow for adequate continuity of care; hence, improvements can be made to the current documents both for ultrasound and for the gynaecology admission room to avoid human error and discrepancies. Ultrasound reports were previously documented on preformatted A4 sheets. In effect, reports were only available on physical paper. Over the past few months, the department has moved to a paper free system with all reports written online, making them available for review to any member of staff who has access. In this way, ultrasound reports are accessible 24/7 and stored securely.

A suggestion to improve documentation in the future would be to adapt the use of an electronic template system for reporting; in this way, reporting of ultrasound would be standardised and universal. Not using such methods could lead to inappropriate decision making. A section for a pregnancy of unknown location or possible EP could be added to the electronic documentation. This section would include a yes and no tick box for ‘moving separate to ovary’, ‘foetal pole present’, ‘foetal heart rate’ and ‘intrauterine pregnancy’. The size of the adnexal mass should also be documented. An example of such a template can be found in Supplementary Annex 1.

Another suggestion to avoid future inconsistency in documentation would be to update the current gynaecology admission sheet used in the admission room at Mater Dei.
Common signs and symptoms could be documented accordingly on history taking and noted in their respective sections and simply ticked when present. This would decrease the risk of omitting information during history taking and create a more standardised approach. An example of such an updated sheet can be found in Supplementary Annex 2. Moving to an electronic paper free documentation method would further improve the system.

However, despite the improvements that can be made to the system the audit also demonstrates the ease of access to healthcare and emergency services available in Malta. This was clear as only one patient presented as an emergency with a ruptured ectopic, whilst all other cases had been picked up beforehand. The majority of patients were managed in the correct and most conservative manner, demonstrated clearly by the use of laparoscopic treatment in most cases.

In conclusion, it is important to highlight that Malta has a population of approximately 500,000. One national hospital exists and this hospital provides for the entire island. The Obstetrics and Gynaecology Department is situated at the national hospital. This department provides services for all acute and chronic conditions in Malta. All ectopic pregnancies or pregnancy of unknown origin pass through this hospital. A national guideline regarding diagnosis and management of EP has not been implemented. The purpose of this audit was to provide standardised care in effect improving patient care, patient satisfaction with an intention of improving patient outcomes. A re-audit is essential once more data are available. This audit will provide enough evidence that a guideline regarding diagnosis and management of EP is required. Improving care standards improves patient satisfaction and helps to continuously offer the best and most up to date service possible, decreasing morbidity and mortality.

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