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Economic evaluation of diagnosing and excluding ectopic pregnancy

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Abstract

Background—The diagnosis of ectopic pregnancy in women presenting in early pregnancy is often protracted, relying on costly investigations that are psychologically burdensome to the patient. The aim of this study was to evaluate the financial costs to the health services in Scotland of the current methods used to diagnose and exclude ectopic pregnancy, and compare these with that of a theoretical single diagnostic serum biomarker.

Methods—We conducted a retrospective cost description analysis (with and without costs of diagnostic laparoscopy) of the healthcare costs incurred by all patients presenting to a large Scottish teaching hospital between June and September 2006 with pain and bleeding in early pregnancy, where ectopic pregnancy was not excluded. Additionally, a cost minimisation analysis was performed of the costs of current ectopic pregnancy investigations versus those of a theoretical single diagnostic serum biomarker. This included sensitivity analyses where the biomarker was priced at increasing values and assumed to have less than 100% diagnostic sensitivity and specificity.

Results—175 patients were eligible to be included in the analysis. 47% of patients required more than 3 visits to diagnose or exclude ectopic pregnancy. The total yearly cost for diagnosing and excluding ectopic pregnancy was £197K for the hospital stated, and was estimated to be £1,364K for Scotland overall. Using a theoretical diagnostic serum biomarker we calculated that we could save health services up to £976K (lowest saving £251K after subanalyses) every year in Scotland.

Conclusions—Ectopic pregnancy is expensive to diagnose and exclude, and the investigation process is often long and might involve significant psychological morbidity. The development of a single diagnostic serum biomarker would minimise this morbidity and lead to significant savings of up to £1 million pounds per year in Scotland.

Keywords

Ectopic pregnancy; biomarker; cost analysis; diagnosis

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Introduction

Ectopic pregnancy is a considerable cause of morbidity and mortality (Farquhar, 2005; Walker, 2007). UK data from the confidential enquiry into maternal deaths demonstrates a static number of deaths from ectopic pregnancy over the past twenty years (Saving Mother's Lives, 2008), with the rate of ectopic pregnancy remaining unchanged at around 1.5% of pregnancies, or even slightly increasing (Seror, 2007).

Despite medical advances, the diagnosis of ectopic pregnancy in women presenting in early pregnancy remains difficult. The majority present with pain and bleeding, common symptoms which can also be incidental, or due to miscarriage (one in five pregnancies). Currently we rely on a combination of serial serum beta-human chorionic gonadotrophin (hCG) levels and ultrasound to differentiate ectopic from intrauterine gestation. These tests are time-consuming and costly for the health services and likely to be psychologically burdensome to the patient. Despite advances in scanning in practice, less than 50% of ectopic pregnancies are diagnosed at the initial visit, and laparoscopy is occasionally needed to confirm the diagnosis, a procedure that involves risk to the patient and considerable expense for the health services (Robson and O'Shea, 1996; Munro et al, 2008).

Consequently, over 20 serum biomarkers have been identified to date in an attempt to permit earlier diagnosis of ectopic pregnancy, the instigation of earlier management and reduce healthcare costs (reviewed in Cartwright et al., 2009). Disappointingly, the clinical utility of these biomarkers has been limited because of variable results due, for the most part, to limitations in study design. In many studies, the cohort that was examined was very small and the prevalence of ectopic pregnancy within the study population was not constant. In some studies, patients were not accurately matched for gestation (in part due to the general nature of an ectopic pregnancy, which is typically difficult to age). Some of the serum biomarkers also limited their own use, as they did not follow a steady pattern (increase or decrease) with normal a normal gestation. Furthermore, changes in the serum assays and the reagents used to detect the biomarkers over the decades have also led to differing results between the studies. We are therefore undertaking a biomarker discovery programme, using carefully selected cohorts of women and microarray technology in Edinburgh, in an attempt to overcome previous limitations in study design with a view to facilitating the rapid and accurate diagnosis of tubal ectopic pregnancy (Horne et al, 2008; Horne et al, 2009).

Recently there has been increased emphasis on resource allocation approaches to maximise the health of the population given the limited resources available. Optimum or 'well-informed' decisions regarding resource allocation requires the costs and benefits of alternative strategies to be considered within a systematic framework (McIntosh and Luengo-Fernandez, 2006; Cochrane, 1972). The National Institute of Clinical Excellence (NICE) in the UK recommends that economic evaluations address the costs incurred (or saved) by its National Health Service (NHS) (NICE, 2004).

The aim of this study was to: (i) perform a cost-description analysis of the current methods used to diagnose or exclude ectopic pregnancy, and (ii) to use a cost-minimisation analysis approach to compare current costs against estimated costs for a theoretical single diagnostic serum biomarker.

Materials and methods

Study population and data collected

A retrospective analysis was conducted of all women with symptoms of pain and bleeding in early pregnancy presenting to the Pregnancy Support Centre at the Royal Infirmary of

Edinburgh (RIE) (a large Scottish teaching hospital) between 1st June 2006 and 30th September 2006. Management was protocol-based, reflecting experience of managing a large population of women in early pregnancy and current practice. On admission all patients had an ultrasound scan and/or serum human chorionic gonadotropin (hCG) level. If the scan showed either an empty uterus, or small intrauterine sac but no fetal pole or yolk sac was identified, and/or hCG levels were inconclusive, then the woman was either classified as 'suspected ectopic pregnancy' (diagnostic) or 'ectopic not excluded' (non-diagnostic). The study comprised all women classified in these categories. Comprehensive care pathway data were collected for each woman in the study group. This information included any further hospital visits, ultrasound scans (transabdominal and transvaginal), serum hCG blood tests, endometrial biopsies, doctor consultations and laparoscopies performed. Doctor consultations were only included where the primary aim was diagnosis and not management. Similarly, laparoscopy was only included if the primary aim as an investigation was of diagnosis (albeit in some cases the laparoscopy was used for management as well).

Cost-description analysis

The costs were assessed from the point of view of the NHS in the UK. This incorporated only the costs directly attributable to the NHS, including staffing (nurses' and doctors' time), investigations (measurement of serum hCG levels, ultrasound scans, endometrial biopsies and laparoscopies), consumables and overhead costs (Drummond et al, 2005). Unit costs were defined using ISD Scotland prices (www.isdscotland.org) for April 2006 – March 2007, specific to the RIE, Edinburgh, taking the figures for net cost per attendance (see Table I). Costs that were not specified by ISD Scotland (endometrial biopsy and diagnostic laparoscopy) were obtained from a previously published economic study undertaken at the RIE (Critchley et al, 2004), a strategy recommended by Drummond et al, 2005. The direct financial costs of the investigations these patients underwent were calculated by multiplying the quantities of resources used by the unit costs of the resources (Johnson et al, 1999). The total cost for patients at the first visit was calculated and a mean cost per patient for that visit was determined. The same calculation was undertaken for all patients attending for second, and subsequent, visits. A cumulative cost for each additional visit was calculated as the sum of costs from each visit of the diagnostic pathway, and a mean cost per patient per number of visits required was found. All costs were expressed in Pounds Sterling (£) and rounded up to the nearest £. Where the costs are in thousands, the letter 'K' denotes thousand. The total cost for all of the visits' investigations for the four months was extrapolated to estimate the cost of diagnosing or excluding ectopic pregnancy over one full year. Data from ISD Scotland on the rates of ectopic pregnancy recorded 747 ectopic pregnancies in Scotland during 2006 (Scottish Morbidity Record databases, SMR01 and SMR02, for 2006, ISD Scotland). Using this data a ratio was calculated for the estimated annual rate of ectopic pregnancies at the RIE relative to that of Scotland. This was then used to extrapolate our figures further to the whole of Scotland to provide an estimate of the financial cost of investigations for ectopic pregnancies nationwide for 2006.

Cost-comparison analysis: current investigations versus a theoretical single diagnostic serum biomarker

A cost comparison was performed between the current ectopic pregnancy investigations versus those of a theoretical single diagnostic serum biomarker (Horne et al, 2008; Horne et al, 2009; Cartwright et al, 2009) costed at the same price as a routine hCG (£0.43). In this scenario each patient was taken as having one nurse-led clinic visit with an ultrasound scan and a single blood test. The cost comparison was performed as a cost-minimisation analysis as the outcomes of both diagnostic pathways are the same.

Sensitivity analyses

A sensitivity analysis examining pricing the biomarker at increasing values from £0.43 (current cost of serum hCG test) to £200 was conducted, and the cost difference was calculated compared to the cost at present. Additional sensitivity analyses, based on the assumption that the biomarker will have a sensitivity and specificity of less than 100%, were also conducted by recalculating the costs using the assumption that varying proportions (say 10, 20 and 40%) of women will need more than one visit (for example, when the biomarker results might still be equivocal).

Results

1162 patients presented to the RIE between 1st June 2006 and 30th September 2006 with symptoms of pain or bleeding in early pregnancy. Following an ultrasound scan, or in some cases hCG serum level (if they presented too early for a scan or they presented out of hours when the ultrasound service was not available), 180 patients were categorised as 'diagnostic' or 'non-diagnostic.' Five of these patients completed their diagnostic pathway after the specified timeframe and were therefore excluded from the total costs. Of the 175 patients included in the cost description analysis, six were managed as an ectopic pregnancy at their first visit, nine were lost to follow-up, and 160 went on to have further investigations. Of the nine lost-to-follow-up, there were four who moved away and attended a hospital elsewhere, four who did not return anywhere for a second appointment, and one who was monitored by hCGs by her GP.

Figure 1 shows the diagnostic pathway for the 175 patients. All pathways began with presentation to hospital. During each visit a certain number of ectopic pregnancies were identified and treated, and a certain number of pregnancies were confirmed as either viable, miscarriage, or given another diagnosis. Those patients with confirmed diagnoses were then removed from the diagnostic pathway. Figure 2 shows the cumulative number of patients who were diagnosed 'ectopic' or 'discharged', and the number continuing 'non-diagnostic' across successive hospital visits. In total, 36 ectopic pregnancies were identified over the four months.

The investigations needed by the 175 patients up until they were given a diagnosis are presented in Table II. Total costs of the investigations used were calculated depending on the number of visits needed. The mean cost per patient who has one visit and the cumulative costs for subsequent visits were then calculated (Table II). As expected, costs per patient increased with number of visits. Laparoscopy was particularly expensive but was only included in costs if used as a diagnostic tool. In all but one case, patients undergoing laparoscopy were confirmed to have ectopic pregnancy.

Based on these figures, we estimated that the total yearly cost for diagnosing and excluding ectopic pregnancy at the RIE to be £197K. Using further epidemiological data from ISD Scotland, we extrapolated this value to the whole of Scotland and estimated the total yearly cost for diagnosing and excluding ectopic pregnancy in Scotland to be £1,364K.

The cost comparison revealed that using a theoretical diagnostic serum biomarker the total yearly cost for diagnosing and excluding ectopic pregnancy in Scotland would be £387K and therefore such a test could save the NHS £976K over the year in Scotland (at 2006 costs).

We acknowledge that all samples are subject to sampling error and chained error potential. The figure for ectopic pregnancy (36/175) has a 95% confidence interval (CI) for events (ectopic pregnancy diagnoses) of 24 to 48 in four months and 72 to 144 per year.

Conducting the cost description using these figures gives the range of possible cost estimates of diagnosing and excluding ectopic pregnancy to be: £1,023K to £2,045K per year in Scotland (Kirkwood and Sterne, 2003).

In addition, we conducted a sub-analysis including the five women who had been excluded as their pathway finished outside of the timeframe. In this scenario the total yearly cost for diagnosing and excluding ectopic pregnancy in Scotland was £1,354K. In this case the NHS saving by using the theoretic diagnostic serum biomarker is estimated at £977K.

The surprisingly high diagnostic rate of laparoscopies suggested that the presumption of use for diagnosis was not as high as ascertained from the notes. We therefore also conducted a separate cost description analysis without including the laparoscopy costs on the basis of assuming that laparoscopies were not entirely diagnostic and more likely to be therapeutic (Table III). This made the total yearly cost for diagnosing and excluding ectopic pregnancy in Scotland £1,085K. In this case, the NHS saving by using the theoretic diagnostic serum biomarker is estimated at £698K.

A sensitivity analysis was performed comparing the money saved in Scotland per year by costing the serum biomarker at £0.43, £10, £100, £150 and £200 (Table IV). These costs would allow for the serum biomarker to be analysed using more expensive techniques including polymerase chain reaction, for example. In addition, a separate sensitivity analysis was conducted to investigate the money saved in Scotland per year by using a serum biomarker that was not 100% sensitive. This was performed by assuming 10, 20 and 40% of women needed 2 or 3 visits to make a diagnosis (see Table V).

Discussion

This study offers novel information on the economic cost of investigating ectopic pregnancy which as far as we are aware has not been calculated previously. It provides a descriptive account of the costs to NHS Scotland of diagnosing and excluding ectopic pregnancy under the current care pathway approach to management, showing that ectopic pregnancy is expensive to diagnose and exclude, and the investigation process may be long and thus involve significant psychological morbidity. In addition, it demonstrates that the development of a single diagnostic serum biomarker test to diagnose/exclude ectopic pregnancy at presentation would minimise this morbidity and save the NHS around £1 million per year in Scotland. This has important implications for the improvement of diagnosing ectopic pregnancy and patient well-being in an economic environment where resources are limited.

Overall we showed that nearly half the patients (47%) required at least three visits in order to diagnose or exclude ectopic pregnancy. As expected, laparoscopy raised the mean cost the most, however, cost of diagnosis predictably increased with visit number. Therefore, development of a single serum biomarker which would require one visit to diagnose ectopic pregnancy would be substantially advantageous financially, particularly if it cost £10 or less (see sensitivity analysis). However, sensitivity analyses also show that even if the biomarker was more expensive (for example, to cover laboratory costs and individual technician supervision), or not 100% sensitive, and a proportion of women required further visits, the results continue to demonstrate a significant saving to the NHS.

We have tried to eliminate bias as far as possible from our estimates for the RIE, and for Scotland, however, the extrapolated figures represent estimates. By calculating the confidence intervals and conducting the subanalysis, including the costs of the pathways for the five women who completed their pathway after the time window had elapsed, we demonstrate that the total costs do not change significantly. The subanalysis of the results

also demonstrates that the total cost remains high even when the costs of the diagnostic laparoscopies are not included (allowing for the fact that they were not solely used for diagnostic purposes). It is however likely that the pattern of care at a tertiary centre, such as the RIE, is different to that in a more rural location (i.e. laparoscopies are used more often for diagnostic purposes) and that inclusion of laparoscopic costs is pertinent. We have not included bed-night costs as we were only looking at diagnostic costs. However, as PSC care is not 24 hour, some patients are admitted and stay in the ward over night. In rural areas, more patients may be admitted overnight and further increase the cost.

Several positive methodological aspects of this study merit discussion. One of its strengths is that it is a thorough retrospective analysis of all of the patients that presented during the specified time period (the dataset was completed with no missing values). A second strength was that it used a national hospital-cost database to provide estimates of costs representative of the situation throughout the UK (www.isdscotland.org) (Seror et al, 2007) A further strength was that the method used in the economic evaluation (a cost-minimisation analysis of the present investigation route and that of a theoretical new biomarker) is part of a cost-effectiveness analysis and represents a full economic evaluation (the optimum comparative analysis of alternative courses of action) (Drummond et al, 2005). The majority of cost-effectiveness analyses have been conducted on treatment/intervention strategies where outcome may be measured. However, in an analysis of investigations, such as that performed in this study, it is harder to define a suitable effect (the outcome of diagnosing an ectopic pregnancy is intrinsically dependent on the investigation).

Nonetheless, our study has limitations as it was not population-based and therefore extrapolation to nationwide areas is only an estimate. Despite this drawback, the method used for extrapolation was based on a ratio of the number of ectopics diagnosed at the RIE compared to Scotland where a value was obtained from the SMR system. It has been found that the rate of ectopic pregnancy recorded in the SMR system underestimates, as it only include inpatients and more patients are cared for on an outpatient basis. This suggests that the study actually underestimates the cost of diagnosing and excluding ectopic pregnancy in Scotland. We also acknowledge that endometrial biopsy and laparoscopy costs were taken from a different source and discounting has not been applied, however, the likelihood is this would only increase the cost further. Furthermore, the diagnostic pathway in this evaluation is used by the main teaching hospital in Edinburgh. Early pregnancy units throughout Scotland will use slightly different diagnostic pathways. Nevertheless, the pathways are all based on nationally agreed evidence-based guidelines (RCOG 2004) and so it is unlikely that they differ extensively.

Another limitation is that the serum biomarker is only in the developmental stage and the cost was approximated to that of clinical chemistry at present. However, sensitivity analyses of increasing biomarker costs indicated that a significant financial benefit could still obtained. Additionally, the biomarker was given 100% sensitivity and specificity which may not be realistic. However, given the substantial savings indicated, a financial benefit may still be inferred even with considerably lower sensitivity and specificity.

The investigative procedures may have further important financial consequences for the patient or caregiver, for example in travel and time costs, which will not be taken into account using this narrower perspective of only direct healthcare costs. Wider perspectives take account of direct costs (medical and non medical) and indirect costs (productivity costs due to mortality and morbidity). These include other direct costs such as those of related services (ambulance services), the costs to the patient and family to come to the hospital and drugs that are purchased over the counter (for example, for pain following an uncomfortable procedure). The indirect costs include the costs to patient/family through time lost from

work (opportunity costs) and those additional costs of being in hospital such as childminding. Women affected by ectopic pregnancy are at the stage in life where they are most affected by this as they are likely to work, or have a family, or both, making these indirect costs extremely significant.

Furthermore, it is likely that multiple hospital visits and tests also have a psychological impact on patient wellbeing. Therefore, the development of a new diagnostic biomarker has the potential not only to save money for healthcare services but also save have benefits both financially and psychologically for patients and families.

In summary, ectopic pregnancy is expensive to diagnose and a serum biomarker would be a cost-effective alternative by maximising the health outcomes within limited health services' budgets, and therefore maximising the welfare of society within resources available (Byford and Raftery, 1998). More research is required to develop such a test, or multiple tests, or other imaging modalities to improve the diagnosis of ectopic pregnancy.

Acknowledgments

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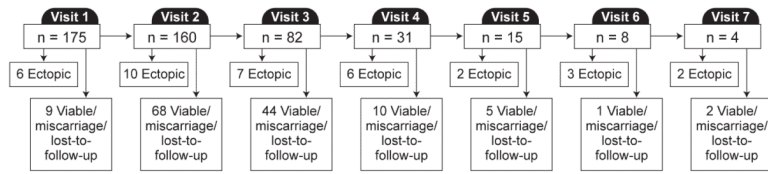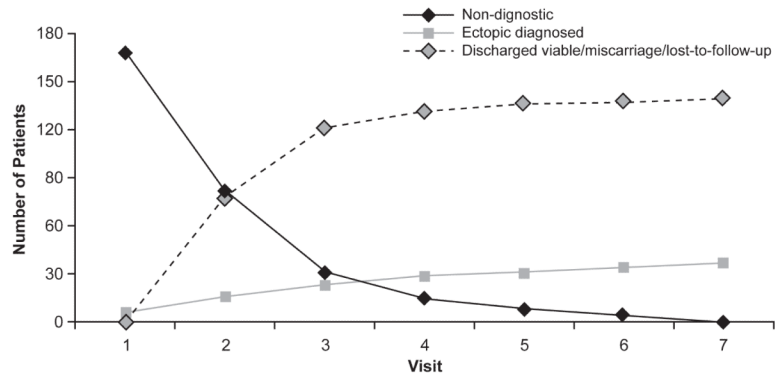
Figure 1.
Diagnostic care pathway for 175 patients.

Figure 2.
Cumulative number of patients diagnosed 'ectopic' or 'discharged', and number continuing as 'non-diagnostic' across successive hospital visits.

Table I

Investigation	Clinical Chemistry (serum hCG level)	Nurse-led clinics (pregnancy support centre appointment)*	Outpatient consultant clinics ('doctor review')	Ultrasound scan (radiology services)	Endometrial biopsy**	Diagnostic laparoscopy**
Cost (£)	0.43	65.00	163.00	41.27	64.68	1218.38

*
includes the costs that contribute to the expense of hospital care such as salaries, medical consumables, equipment and logistics costs e.g. laundry, administration.

**
includes all costs of medical staff, nurses, capital, equipment, disposables and pathology.

Table II

Costs incurred categorised by number of visits

Visit	Patients (n)	Costs (£)						Mean visit cost per patient	Cumulative mean visit cost per patient
		Nurse consult	USS	HCG	Biopsy	Doctor consult	Laparoscopy		
1	175	11375	6149	73	0	3097	3655	139	139
2	160	10400	1651	54	129	3423	7310	144	283
3	82	5330	1156	30	65	1956	2437	134	417
4	31	2015	537	9	129	1304	0	129	545
5	15	975	165	5	65	489	0	113	659
6	8	520	124	3	65	489	0	150	809
7	4	260	41	1	65	163	0	133	941

Table III

Costs incurred, excluding laparoscopy, categorised by number of visits

Visit	Patients (n)	Costs (£)						Mean visit cost per patient	Cumulative mean visit cost per patient
		Nurse consult	USS	HCG	Biopsy	Doctor consult			
1	175	11375	6149	73	0	3097		118	118
2	160	10400	1651	54	129	3423		98	216
3	82	5330	1156	30	65	1956		104	320
4	31	2015	537	9	129	1304		129	449
5	15	975	165	5	65	489		113	562
6	8	520	124	3	65	489		150	712
7	4	260	41	1	65	163		133	845

Table IV

Sensitivity analysis comparing £ saved in Scotland per year at increasing serum biomarker costs

Serum biomarker cost (£)	0.43	10.00	100.00	150.00	200.00
£ saved in Scotland per year	976,079	941,328	614,516	432,953	251,391

Table V

Sensitivity analysis comparing £ saved in Scotland per year using a serum biomarker (costed at 0.43) at decreasing sensitivity by increasing % of women requiring more visits

Visit number	2 visits			3 visits		
% of women requiring more visits	10	20	40	10	20	40
£ saved in Scotland per year	935,480	897,136	818,192	896,374	821,097	666,116