Are national recommendations regarding examination and disposal of products of miscarriage being followed? A need for revised guidelines?

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BACKGROUND: National guidance documents advise that tissue obtained from treatment of miscarriage should be submitted for histological examination to exclude trophoblastic disease and ectopic pregnancy, and require sensitive disposal of human tissue. The aim of this study was to determine the extent to which health professionals have adopted these recommendations.

METHODS and RESULTS: Fifteen Scottish Obstetric and Gynaecology services participated in an audit of early pregnancy loss care. Three audit tools were used. In a case note review, 484 women completed medical or surgical treatment for miscarriage. 71% of records contained evidence of histological examination of tissue. Documentation of discussion of disposal of tissue with the woman was found in 29% of records. In a patient survey, 648 women with threatened or confirmed miscarriage returned questionnaires. Active treatment occurred in 134 cases. Only 55%, 50.9% and 47.4% reported being ‘informed’, ‘consented’ and ‘involved’, respectively, with decisions about tissue disposal. In a staff survey, a postal questionnaire was administered to 224 gynaecologists, with 144 replies. Self reported practice as ‘seldom’ or ‘occasional’ for sending tissue for histological examination was 34% for surgical evacuation and 57% for medical management. Reporting of ‘seldom’ or ‘occasional’ discussion of disposal of tissue with the woman was 42% and 49% for surgical and medical treatment, respectively.

CONCLUSIONS: National guidance on these issues was found to be contentious and implementation was variable. Wide consultation with stakeholders is needed prior to the publication of revised guidance.

Key words: clinical guidelines/miscarriage/pathology/quality of care

Introduction

The Royal College of Obstetricians and Gynaecologists (RCOG) has published guidance on the management of early pregnancy loss and recommends that all women undergoing medical or surgical evacuation for miscarriage should have pregnancy tissue sent for histological examination (Hinshaw and Fayyad, 2000). Within Scotland, the National Medical Advisory Committee published guidance that all previable fetuses should be disposed of in a dignified and respectful way, regardless of gestational age or the way in which the loss occurred. The wishes of the woman and her partner should be taken into consideration (Anonymous, 1997a). This paper describes our findings in relation to these two recommendations in Scottish Obstetric and Gynaecology services.

Methods

Fifteen obstetric and gynaecology services in Scotland, involving 18 hospitals, participated in an audit addressing many aspects of early pregnancy care that have been reported in full elsewhere (Anonymous, 2003). These services were selected to represent the range of settings in which obstetric and gynaecology services are provided within Scotland, including University Teaching Hospitals, large district general hospitals (defined as > 250 miscarriages per year), small district general hospitals (< 250 miscarriages per year), remote and rural services, and split-site services. Three components of the broader audit assessed disposal of products of miscarriage: a retrospective case note review (934 records), prospective patient survey (648 women) and a staff postal survey (144 consultant and middle grade medical staff).

Case note review

All women managed for miscarriage (01/02/02–31/07/02) were identified from ward and theatre registers. Epi-Info 2000 (CDC, Atlanta, USA) was used to calculate hospital-specific sample sizes providing 80% power, with 95% confidence, that a measured proportion would be within 10% of the ‘true’ value. Within each hospital, a sample of the relevant size was randomly selected for review from all identified cases. Overall, 942 case notes were sought and 934 were obtainable for review. Trained audit assistants extracted
data onto standardized proforms. Histological examination of miscarriage tissue was coded as having occurred if a pathology report could be found in the notes, or if a comment was made within the case record or operation note that tissue was sent for histology. Evidence of discussion with the patient about disposal of pregnancy tissue was sought within the records. Services have been anonymized, using a number from 1 to 15, within this paper.

**Patient survey**

Multi-centre research ethics committee approval was obtained prior to administration of the patient survey. Questionnaires were administered at discharge from hospital to women with confirmed early pregnancy loss (<14 weeks gestation) or with a threatened first trimester miscarriage during a 4-month period from 1st December 2002. Women were asked to complete the questionnaire and return it in a business reply envelope. Non-responders were considered to have withheld consent and consequently there was no opportunity to re-mail them. In relation to histological examination of pregnancy tissue, women were asked three questions: (i) Were you informed of what happens to any pregnancy tissue obtained during treatment? (ii) Did the staff seek your consent (either verbally or in writing) as to what happens to any pregnancy tissue obtained? (iii) Were you involved with the decision about what happens to any pregnancy tissue obtained?

Results from all services have been aggregated.

**Staff survey**

Obstetric and gynaecology consultants and middle grade medical staff (associate specialist, staff grade and specialist registrars) involved with the management of early pregnancy loss within the 15 services were identified by discussion with local lead clinicians. A questionnaire was mailed to them in December 2002 asking how often they would arrange histological examination of products of conception (if they were obtained) at surgical or medical management of miscarriage. In addition, they were asked to indicate how often they would inform the patient of what happens to tissue obtained from these treatments. Two reminders were sent in January 2003.

Patient and staff questionnaire responses were entered into an Access database and analysed using SPSS software v10 (SPSS, Chicago, IL) and confidence interval analysis disk v 2 (BMJ Books, London, UK). The 95% confidence intervals for proportions were calculated using Wilson’s method.

**Results**

**Case note review**

Case records of 934 women were reviewed. Of these, active treatment (rather than expectant management) was completed by 484 women (424 surgical evacuation, 60 medical evacuation).

**Histological examination**

A total of 21 case records were excluded from analysis (three proforms had missing data and tissue was not obtained from 18 patients after treatment). Compliance with the RCOG recommendation for sending tissue for histological examination in individualized services is summarized in Figure 1. Overall, 71.1% (95% CI 66.8–75%) of records had documentary evidence of histological examination. The median service was number 14 with 82.9% of case records containing evidence of histological examination. One third of services had <50% documentation of histological examination. One third of services had <50% documentation of histological examination.

**Discussion of disposal of pregnancy tissue**

Poor documentation of any discussion with the patient concerning disposal of pregnancy tissue was found in most services (Figure 2). Overall, only 29% (95% CI 25–34%) of case records contained any form of documentation, and the median service reported a level of only 14% (service 11).

**Patient survey**

A total of 1750 questionnaires were distributed, with 648 returned, representing an overall response rate of 37%. The 648 responders comprised 323 women with pregnancy loss, 307 women with threatened miscarriage (i.e. viable pregnancy at discharge), 15 women who were unsure of their diagnosis at discharge, and three women who left the ‘diagnosis’ question blank. Response rates varied among O&G services, from 20 to 61%, with numbers of returned questionnaires from 2 to 94. A total of 134 women underwent active treatment (98 by surgical evacuation and 36 by medical methods). Of these women, 10 reported that no tissue was obtained during treatment, 81 reported tissue obtained, 40 reported they did not know if tissue was obtained and three women left this question blank.
Involvement in decisions about disposal of pregnancy tissue

For the ‘informed’, ‘consent’ and ‘involved’ questions there were 120, 114 and 116 replies, respectively, from women who had undergone active treatment for miscarriage. Women who reported that no tissue was obtained were excluded from this analysis. Only 55% (95% CI 46.1–63.6%), 50.9% (95% CI 41.8–59.9%) and 47.4% (95% CI 38.6–56.4%) of women reported that they were ‘informed’, ‘consented’ and ‘involved’ with decisions about disposal of pregnancy tissue.

Staff survey

A total of 224 consultants and middle grade medical staff were mailed, with 144 replies, representing a response rate of 64%.

Histological examination

For surgical evacuation, 137 replies were analysed (five replies were blank and two replies stated that they were not involved with this form of treatment), while for medical evacuation, 118 replies were analysed (seven replies were blank and 19 staff stated they were not involved with this treatment). Results are summarized in Table I. We found that 34% of medical staff reported that they ‘seldom’ or only ‘occasionally’ sent products of miscarriage for histological examination after surgical evacuation. For medical evacuation, reporting of ‘seldom’ or ‘occasional’ examination was 57%.

Discussion of disposal of pregnancy tissue

For surgical evacuation, 131 replies were analysed (six replies were blank and seven staff stated they were not involved with this treatment), while for medical management 113 replies were analysed (eight replies were blank and 23 staff stated they were not involved with this method of treatment). Results are summarized in Table I. We found that 42% of medical staff reported that they ‘seldom’ or only ‘occasionally’ discussed disposal of products of miscarriage with women and their partners prior to surgical evacuation. A similar finding was found for medical evacuation, with 49% of medical staff reporting ‘seldom’ or ‘occasional’ discussion with women.

Discussion

Within this audit, we found low compliance with two recommendations from national guidance documents. Why might this have happened?

Various barriers to the implementation of guidelines have been described (Foy et al., 2001). Guideline development is problematic for topics where the evidence base is limited. With a lack of good evidence, one might expect to find a greater proportion of clinicians disagreeing with a recommendation and not complying with it. An additional problem for implementation is that guidelines are produced by a multiplicity of agencies; some, from professional societies, can only be viewed as advisory whereas those from government agencies, for example the National Institute of Clinical Excellence, may be mandatory.

The recommendation by the RCOG to send all products of miscarriage for histological examination is ‘Grade C’, derived from the opinion of an expert group—the 33rd Study Group (Anonymous, 1997b). The rationale behind this recommendation is to exclude ectopic pregnancy and trophoblastic disease. Within the RCOG guideline, evidence from one study that concludes that routine histological examination is not needed is presented in a manner that argues that tissue should be sent (Heath et al., 2000). This prospective observational study involved 1576 women undergoing termination of first trimester pregnancy and emergency surgical uterine evacuation. All women with molar changes (two cases) had been diagnosed by ultrasound pre-operatively. Two of 468 women undergoing surgical evacuation for a presumed diagnosis of miscarriage were found to have an ectopic pregnancy at day 25 and 28 post-evacuation. Both women presented with abdominal pain and were treated surgically without complication. The study authors conclude that targeted histological examination is appropriate, and should be performed when there is ‘an uncertain pre-operative diagnosis, when less tissue than expected has been obtained, when trophoblastic tissue is not readily identified at surgery, or if routine inspection during the operation suggests that there may be unexpected pathology.’

In contrast, the RCOG view is that the maternal risks from ectopic pregnancy justify a policy of universal histological examination and that the presence of decidua only should alert the clinician to reconsider his diagnosis of the type of early pregnancy loss. However, a prospective study of 676 women undergoing early surgical termination of pregnancy comparing immediate fresh tissue examination by the surgeon with routine pathological examination found three potentially life threatening conditions (Paul et al., 2002). One patient had a molar pregnancy diagnosed by histopathological examination only. Two (0.3%) women had ectopic pregnancies. Both were reported, by the surgeon, at surgical

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evacuation as minimal tissue seen, but in one case the pathologist noted ‘rare villi’. Consequently, the authors suggest that pathological examination may lead to misdiagnosis or a delay in diagnosis of ectopic pregnancy.

Fear of litigation if failure to send products of miscarriage for histological examination led to a delay in diagnosis of either trophoblastic disease or ectopic pregnancy is a reason some ‘experts’ use to justify sending all products from miscarriage for histological examination. However, this medicolegal argument should not be used as a basis for a guideline recommendation.

There are practical difficulties with compliance with current RCOG recommendations. Many pathology laboratories are under considerable pressure in providing a service to the local community, with a continued shortage of trained pathologists. Sending all products of miscarriage to pathology departments carries an opportunity cost (Palmer and Raftery, 1999) in terms of the resources used, including the pathologist’s time. Cost–utility analysis to compare healthcare options has been used in health technology appraisal by the National Institute for Clinical Excellence (NICE) and NHS Quality Improvement Scotland (National Collaborating Centre for Women’s and Children’s Health, 2004) (Ritchie et al., 2004). Within a resource-constrained health service, the use of such economic analysis could assist professional organizations, such as the RCOG, in developing guidelines. We were unable to identify any form of economic analysis comparing policies of routine histological examination and selective examination of products of miscarriage.

Furthermore, the RCOG guidance document suggests that conservative methods of miscarriage management are effective. If, increasingly, women are managed using a ‘wait and see’ approach then they will complete their miscarriage at home. In these circumstances, it seems unlikely that pregnancy tissue can be examined histologically. But, if one believes we must exclude trophoblastic disease then one could argue that women should only be allowed to miscarry at home if they agree to return tissue to the pathology laboratory for processing.

Discussion about sensitive disposal of fetal material began with the Polkinghorne report which stated ‘on the basis of its potential to develop into a human being, a fetus is entitled to respect, according it a status broadly comparable to that of a living person’ (Polkinghorne, 1989). A problem for our study was defining ‘sensitive disposal’. We used the themes of ‘informing’, ‘consent’ and active ‘involvement’ in the decision process by the woman as constituting sensitive disposal. Within our audit, there was poor documentation of discussion with women of what happens to pregnancy tissue. This may be because no discussion occurred or it might reflect poor documentation. However, our complementary patient survey suggests that ~50% of patients stated that they were not informed about disposal of tissue.

The events of Alder Hey, leading to the publication of the Royal Liverpool Childrens Inquiry, have put discussion of what happens to organs and tissue into the medical and political arena (Anonymous, 2001b). A census by the Chief Medical Officer (CMO) of England in 2000 suggested that >54,000 organs, body parts, stillborn children and fetuses were retained and held after post mortem by pathology services in England (Chief Medical Officer, 2001a). The CMO for England’s response to the Alder Hey report states that his recommendations are underpinned by eight guiding principles of respect, understanding, informed consent, time and space, skill and sensitivity, information, cultural competence, and a gift relationship (Chief Medical Officer, 2001b). He recommends that the ultimate disposal of retained tissues, organs, body parts, stillbirths and fetuses should be in accordance with any expressed wishes of the individual or his or her family. In response to this the Department of Health published a consultancy report entitled ‘Human Bodies, Human Choices’ which identified many of the wide issues in changing the law on human organs and tissue in England and Wales (Department of Health, 2002). In December 2003 the Human Tissue Bill was published by the Government with the aim of providing a legislative framework for issues relating to whole body donation and the taking, storage and use of human organs and tissue (Department of Health, 2004). It will lead to the formation of the Human Tissue Authority to regulate these activities. The Bill deals with issues of consent, but it has caused concern in many health professionals, including the Royal College of Pathologists, for its complexity and lack of clarity (Royal College of Pathologists, 2004).

Before the Alder Hey report, the RCOG/RCPath joint working party into fetal and perinatal pathology advised under ‘consent for autopsy’ that ‘although there is no legal requirement, there is an ethical requirement and consent should now be sought for all examinations of all fetal specimens of less than 24 weeks of gestation’ (Anonymous, 2001a). The Royal College of Nurses (RCN) has also published guidance on sensitive disposal and recommends hospital burial or cremation. Private burial or cremation and burial outside a cemetery should also be available for disposing of fetal remains (RCN Gynaecology Nursing Forum Working Group, 2001). Furthermore, the RCN recommends that up to date written information must be provided at the time of miscarriage which includes the options available and the time limits for making a decision.

We acknowledge that there are several limitations with this study, particularly the low response rate to the patient survey, with a high percentage of replies coming from one service. But our complementary case note review and staff survey both showed consistent findings with variable implementation on the issues of histological examination and sensitive disposal.

As a gynaecologist one faces a challenge. We have guidelines that state that all tissue should be sent for histological examination. And yet we have a duty of care to ask women who have lost pregnancies what should happen to that pregnancy tissue. The range of terminology in use to describe the products of miscarriage highlights the problems and limitations that clinicians face in discussing these issues sensitively with women and their partners. Furthermore, pregnancy loss is a highly emotional experience (Lee and Slade, 1996). Satisfaction with information provision may be linked to the type of informational coping style that a patient...
exhibits in a stressful situation. Cancer patients dissatisfied with information provision have been found to report more information-avoiding behaviour than those who are satisfied (Elf and Wikblad, 2001). Some women may want to discuss the fate of the products of miscarriage, but for others we run the risk of adding to their distress.

We believe it is time to consult more widely on these issues. We need to involve users of our services, gynaecologists, nurses, midwives, pathologists, health economists and hospital managers in developing guidance as to what should, and what should not, be done with products of miscarriage. The RCOG has promoted widespread discussion of guidelines prior to formal publication through ‘publication’ on the worldwide web for open peer review. We await an update on the management of early pregnancy loss developed through methods that allow wide stakeholder input.

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References

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