

Peer Reviewed **Original Article****CRITERIA FOR SONOGRAPHIC INVESTIGATIONS OF ECTOPIC PREGNANCIES: A STUDY OF PRACTICE AT A TERTIARY HEALTHCARE FACILITY IN KITWE, ZAMBIA****Munsanje F¹** *PhD Rad* | **Mwaanga M^{2,3}** *BSc Rad.* | **Bwalya M⁴** *MHSc Rad.* | **Loloji B¹** *MPH*¹School of Applied and Health Sciences, Evelyn Hone College of Applied Arts and Commerce, Lusaka, Zambia²Kitwe Teaching Hospital, Department of Radiology, Kitwe, Zambia³Faculty of Medical Radiation Science, Lusaka Apex Medical University, Lusaka, Zambia⁴Department of imaging, St. Francis' Hospital, Katete, Zambia<https://doi.org/10.54450/saradio.2023.61.1.719>**Abstract**

Background. Ectopic pregnancy (EP) occurs when a fertilised embryo implants extra-endometrium. Common symptoms include lower abdominal pain, amenorrhea, and per vaginal (PV) bleeding. Ultrasonography (sonography) plays a positive role in investigating EP.

Aim. The aim of this study was to establish the relationship between the clinicians' provisional diagnosis for EP and the conclusion in the respective diagnostic ultrasound report.

Methods. A retrospective descriptive quantitative study was performed to examine 50 files of women aged 12 to 25 years with lower abdominal pain and a provisional diagnosis for EP. Statistical Package for Social Sciences version 22 (SPSS 22.0) of 2013 and Microsoft Excel 2010™ software facilitated data analysis, guided by the systems theory.

Results. Files reviewed for completeness of clinical information recorded EP signs or symptoms: lower abdominal pain, amenorrhea, pelvic mass, and PV bleeding. The positive laboratory test findings for pregnancy, based on human chorionic gonadotropin (HCG) hormone were also on record in some cases. The files were examined for expressed provisional diagnosis of EP by clinicians and supported by clinical history involving lower abdominal pain (98%), amenorrhea (78%), and PV bleeding (76%). Most files were silent on the question of palpable pelvic mass (90%) and laboratory pregnancy tests (74%), which could have reinforced the provisional diagnosis. The adequacy of clinical information for provisional diagnosis was categorised as adequate, fairly adequate, and inadequate. The sonography requisition forms (SRFs) depicted compliance to compelling clinical details for provisional diagnosis (88%) and reference to previous ultrasound examination (2%). The overall finding showed increased compatibility between provisional diagnosis and sonographic findings for EP in cases with adequately recorded information on clinical history.

Conclusion. This study established that adequate completion of SRFs by clinicians and provision of appropriate clinical information enhanced diagnosis of EP.

Keywords. Beta-hCG, clinical information, extra-uterine pregnancy, systems theory, ultrasonography

INTRODUCTION

Ectopic pregnancy (EP) is a major health problem in women of child-bearing age.^[1,2] For a normal pregnancy process, once the ovary releases an ovum into the fallopian tube, fertilisation takes place when the ovum meets the sperm within the tube.^[2] The fertilised ovum moves into the uterus within 10 days to attach to the endometrial lining within the uterine cavity and continues to grow within the uterus in the

subsequent 39 weeks.^[3] An EP can be tubal (fallopian tube) or non-tubal sited, occurring about 95% and 5%, among EPs respectively.^[2,4,5,6,7] A woman may have intermittent fever, fainting episodes, missed or late menstrual period and palpable pelvic mass.^[2,8,9] Such pregnancies cause abnormal vaginal bleeding in the first three months of pregnancy,^[2] thereby capable of causing maternal anaemia, shock and consequent death.^[2,5] EP may be a healthcare emergency.

An EP is subject to rupture as the pregnancy grows, hence the clinical emergency requiring urgent intervention.^[10] These conditions are mostly encountered in women with a clinical history of pelvic inflammatory disease (PID), pelvic infections, tubal surgery,^[2,7] or in vitro fertilisation (IVF) where the transfer of four or more embryos to the uterus is an additional risk factor.^[11]

Worldwide, the incidence of EP varies with a population, but it has been accounted for 1-2% of all reported pregnancies.^[3,12] In African countries, where some women tend to present for healthcare at the rupture stage of EP, this problem amounts to notable cause of maternal deaths,^[4] with a case fatality rate around 1-3%. This rate is 10 times higher than reported in developed/industrialised countries.^[4,13,14,15] The World Health Organisation (WHO) statistics show EP as a rare condition which affects about 2% of all pregnancies.^[16] An audit of the gynaecology records for 2012 at the University Teaching Hospital in Lusaka, Zambia showed that 197 (3%) EPs out of 6566 gravid women were admitted. Most of these patients required emergency healthcare involving laparotomy and salpingectomy coupled with several days of post-operative care.^[17] Some authors consider EPs among the leading causes of maternal death in the first trimester.^[2,4,18]

Ultrasound examinations have a pivotal role in confirming location of early pregnancies, including EPs,^[2,6,7,19,20] thereby aiding decisions in EPs as life threatening emergencies that require urgent clinical attention in terms of diagnosis and treatment. The responsibility of a practitioner (ultrasonographer) in ultrasound examinations is to provide a required diagnostic ultrasound service involving ultrasound scanning, compilation of annotated images, and a written diagnostic report.^[21] EP indications for ultrasonography are common medical imaging emergencies at the Kitwe Teaching Hospital (KTH) in Zambia. Early detection of EP would primarily depend on the clinical symptoms and signs,^[8] coupled with biomedical laboratory findings, seeking sonographic outcome. However, based on the hospital's radiology records in this study, most of the ultrasonographic results for EP requests were found to be negative. This inconsistency raises interest on the quality of relationships between the clinical questions in the provisional diagnoses that attributed EPs and sonographic conclusions.^[8] The aim of the study was to compare clinical information with sonographic findings to establish criteria in terms of request for EP ultrasound.

MATERIALS AND METHODS

This study was directed to the evaluation of the clinical information and sonographic findings in order to establish the requisition criteria for ruling out or confirming EPs by ultrasonography at hospital obstetrics and gynaecology clinics as well as the out-patient's department at the KTH in Zambia. It was a retrospective descriptive quantitative study, guided by the systems theory. Invitation for participation involved 96 clients referred for ruling out or confirming EPs in the period from 1 January to 31 December 2015.

Inclusion criteria were: women referred for ultrasonography, at the radiology department, by the clinicians querying EP and women in possession of first diagnostic ultrasound results seeking a second opinion; and female clients within the child-bearing age from 12 to 45 years. The participants' average age was 31 years. Exclusion criteria were: women with pelvic pain not suggestive of EP; and provisional EP diagnoses done outside KTH.

Records were retrieved by convenience sampling method and the data entered on a self-designed data collection tool. This process involved collecting information on clinical history raising the clinical question of EP as entered by the clinicians on the patients' records. The clinical information and clinical question as recorded on each request form, and the findings on the sonographic report were collected with the aid of the checklist tool. A pilot study involving three women was undertaken at KTH to ascertain validity and reliability of the research tools.

The data collected from the hospital records were processed using Statistical Package for Social Sciences version 22 (SPSS 22.0) of 2013 and Microsoft Excel 2010™ software to aid analysis in line with the objectives of the study. The results are presented in statistical tables, bar charts, and pie charts, and narrative statements on the displayed data. The charts, graphs and the information in the tables were generated using Microsoft Excel and SPSS.

Ethical approval was obtained from the National Health Research Authority of Zambia (NHRAZ). Authority to conduct the research at KTH was obtained from the KTH Research Committee. The research principle of confidentiality in terms of hospital records and clinical data was adhered to.

RESULTS

• Data realisation

Ninety-six (n=96) women were referred to the radiology department at KTH for EP in 2015. Data analysis was done on 50 (n=50) conveniently retrieved records of women sent for EP. The in-patient register was also analysed for the confirmation of EP results and tracing of file numbers: ten (n=10) for the latter were obtained. The outpatient registers were used to check for the EP patients' hospital numbers for retrieval of their records and 40 (n=40) were found. Final sample comprised 50 (n=50) records in order to analyse adequacy of clinical indications, clinical details on each sonographic requisition form (SRF), and sonography report.

• Adequacy of clinical information

Analysis of clinical data included EP signs and symptoms: lower abdominal pains, amenorrhea, pelvic mass, PV bleeding and positive laboratory pregnancy tests.

• Clinical indications of EP

Data analysis for EP indications were lower abdominal pains (98%) with 2% of the records silent on symptoms of lower abdominal pains. Additionally, in 78% of the records amen-

orrhoea was indicated; 22% of the records did not have this indication. In terms of pelvic mass 90% did not have this indication; 10% did include pelvic mass. PV bleeding accounted for 76% of indications for sonography and 24% did not have indications as in Figure 1. In terms of laboratory pregnancy tests only 26% had such tests.

• Level of adequacy in clinical indications

The indicative information for EP was categorised as: adequate (scores 4/5 to 5/5), fairly adequate (score of 3/5), and inadequate (scores 1/5 to 2/5). These rankings of the total sample (n=50) are in Table 1a which shows adequate

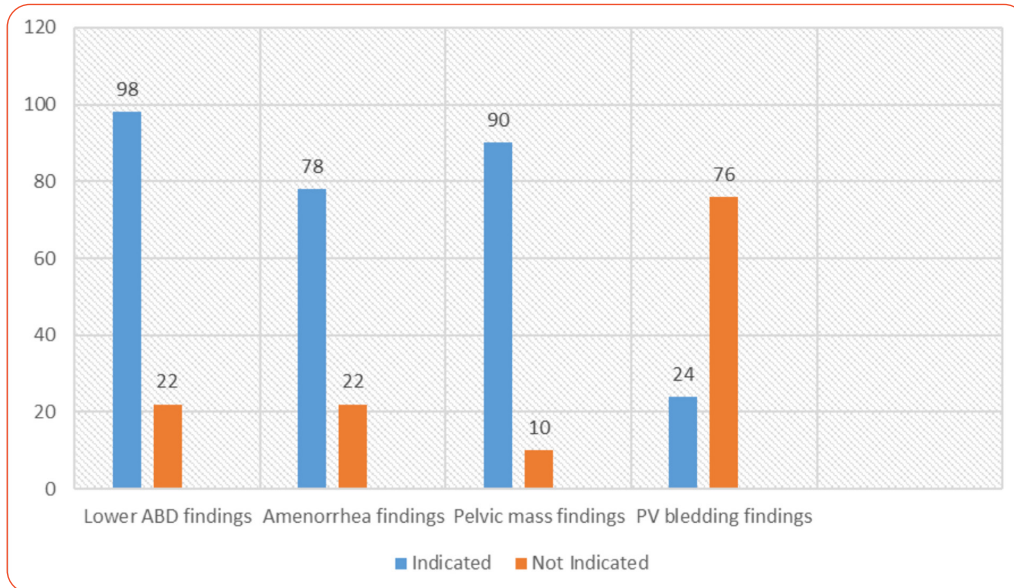


Figure 1. Clinical indicators of ectopic pregnancy: findings in percentage.

Table 1a. Level of adequacy in clinical indications (n=50)

Clinical information adequacy	Clinical indications (counted) for ectopic pregnancy (EP)	Number of EPs by provisional diagnosis (%)	Number of EPs by sonography (%)	Number of EPs by surgery (%)
Adequate	Lower abdominal pain, amenorrhoea, pelvic mass, per vaginal bleeding and positive laboratory pregnancy test (5)	3 (6)	3 (100)	3 (100)
Adequate	Lower abdominal pain, amenorrhoea, per vaginal bleeding and positive laboratory test (4)	1 (2)	1 (100)	1 (100)
Adequate	Lower abdominal pain, amenorrhoea, pelvic mass and per vaginal bleeding (4)	1 (2)	1 (100)	1 (100)
Fairly adequate	Lower abdominal pain, amenorrhoea and per vaginal bleeding (3)	6 (12)	3 (50)	4 (67)
Fairly adequate	Lower abdominal pain, amenorrhoea and positive laboratory test (3)	7 (14)	2 (100)	2 (29)
Fairly adequate	Lower abdominal pain, amenorrhoea and pelvic mass (3)	1 (2)	1 (100)	1 (100)
Inadequate	Lower abdominal pain and amenorrhoea (2)	19 (38)	3 (16)	3 (16)
Inadequate	Lower abdominal pain and per vaginal bleeding (2)	2 (4)	0 (00)	0 (00)
Inadequate	Lower abdominal pain and laboratory test (2)	2 (4)	0 (00)	0 (00)
Inadequate	Lower abdominal pain (1)	7 (14)	1 (14)	1 (14)
Inadequate	Amenorrhoea (1)	1 (2)	0 (00)	0 (00)
	TOTAL	50 (100)	15 (30)	16 (32)

(n=5), fairly adequate (n=14), and inadequate (n=31). Table 1b shows the results of adequate clinical information yielding confirmed EP in ultrasonography finding; fairly adequate clinical information (n=06 Eps) out of 14 sonography investigations. Inadequate clinical indication and clinical information category recorded 4 EP by sonography out of 31 examinations.

• Clinical details on sonographic requisition form

The study considered the clinical information inclined to clients' clinical history, provisional diagnosis, previous ultrasound examination, and laboratory tests/results, which essentially amounted to adequacy of information in the sonographic requisition form (SRF). Table 2 shows the frequency distribution of the completed fields on the SRF. Most clinical details indicated on SRF pointed to provisional diagnosis (100%) and required examination (88%). Table 3 shows that only 2% of the SRFs indicated a previous ultrasound examination.

• Sonographic findings

Sonographic features for EP were: empty uterus, free fluid collection in the Pouch of Douglas, adnexal mass with or without a gestation sac. EP in most (n=15) findings with sonographic features adequately pointing to EP was up-

held in second opinion ultrasound examinations. One (n=1) woman with inadequate clinical information resulted in EP by ultrasonography (Table 1a). An empty uterus was indicated in 86% of the sample; 14% indicated uterine pregnancies. The majority of examinations (68%) showed no adnexal mass/masses; 32% had no convincingly gestation sac. In terms of free fluid collection in the Pouch of Douglas most (60%) were negative. Table 4 shows that a gestation sac was detected outside the uterus in 10% of the examinations.

• Relationship between clinical information and diagnostic output

The availed clinical information was linked to quality of clinical assessments for EP, where the provisional diagnosis validity ranged from 13 to 100%. Table 5 shows results of clinical information in terms of validity of provisional diagnosis of sample (n=50): adequate (n=5/100%); fairly adequate (n=14/43%); and inadequate (n= 31/13%).

• Ectopic pregnancy statistical data

Document analysis of the radiology ultrasound, as well as in-patient gynaecology and obstetrics registers, respectively was undertaken to establish the number of confirmed EPs at surgery: there were 15 (n=15) confirmed EPs out of the total sample (n=50).

Table 1b. Summary of the level of adequacy in clinical indications (n=50)

Level of adequacy	Number of clinical indications	Number of patients	EP sonography confirmation in examined number of patients (%)
Adequate	4 – 5	5 (10%)	5 (100)
Fairly adequate	3	14 (28%)	6 (43)
Inadequate	1 – 2	31 (62%)	4 (13)

Table 2. Completion of sonographic requisition form (n=50)

Item	Fields in the sonographic request form	Clinicians' frequency of completion (%)
1	Name of hospital	100
2	Requesting department	60
3	Hospital Number	44
4	Name of patient	100
5	Age of patient	52
6	Sex of the patient	82
7	Brief patients clinical history	20
8	Previous ultrasound examinations	2
9	Laboratory examination results	6
10	Provisional clinical diagnosis	100
11	Examination Required	88
12	Clinicians name	64
13	Signature	80
14	Date	78

Table 3. Clinical details on sonographic requisition request forms

S/N	Clinical details	Indicated (%)	Not indicated (%)
1	Patients clinical history	20	80
2	Provisional diagnosis	88	12
3	Previous ultrasound examination	2	98
4	Laboratory tests/results	6	94

Table 4. Sonographic findings

S/N	Features	Yes (%)	No (%)
1	Empty uterus	86	14
2	Adnexal mass	32	68
3	Fluid in Pouch of Douglas	40	60
4	Gestation sac outside the uterus	10	90

Table 5. Relationship between quality of clinical information and EP diagnostic output (n=50)

S/N	Clinical information on files	Number of cases	Matching sonography findings with confirmed EPs	Validity of provisional diagnosis* %
1	Adequate	5	5	100
2	Fairly adequate	14	6	43
3	Inadequate	31	4	13
4	TOTAL	50	15	30

*All cases (n=50) had a provisional diagnosis of EP

DISCUSSION

This study was guided by the systems theory, which focuses on the interrelationships among components of a process. This theory, according to Heylighen^[22] is applied by decision-makers in problem-solving while considering specific courses of action. The systems theory (Federal Emergency Management Agency – FEMA, 1999) points to four basic problem-solving elements in addressing a problem or clinical question: (1) input – constituents of problem or question, (2) transformation – technological processes from inputs to outputs, (3) output – factual products or services, and (4) feedback or report – encompassing the interpretation of output with respect to input. This theory takes a coordinated cyclical route from the clinical questions to evidence-backed feedback responding to the question^[23] as illustrated in Figure 2.

Accordingly, EP sonographic investigations thrive on evidence of a patient’s disease pattern/s in sonographic images. With reference to the systems theory, the clinical history

and question constitute the input, with the ultrasound investigations being the technical process leading to factual sonographic data as output. The diagnostic reports (output) are projected as evidence-backed feedback to clinical question/s that characterise the input.

• **Clinical requisition criteria**

This study demonstrated 62% occasions of inadequate clinical data for EP investigations (Table 1b). This gap is in disagreement with a requirement in a study by Bosanquet et al.^[24]; clinicians are required to provide adequate clinical information for the radiological investigations to ascertain the type of examination and avert or curtail errors in diagnosis and consequent patient management. The leading clinical data found in this study was lower abdominal pains (98%) as shown in Table 1a. Classical symptoms and signs of EP being: lower abdominal pain, amenorrhea and PV bleeding, positive laboratory pregnancy test.^[2,7,25] The clinicians’ consideration of clinical indication data for EP mostly points to lower abdominal pain, amenorrhea, and

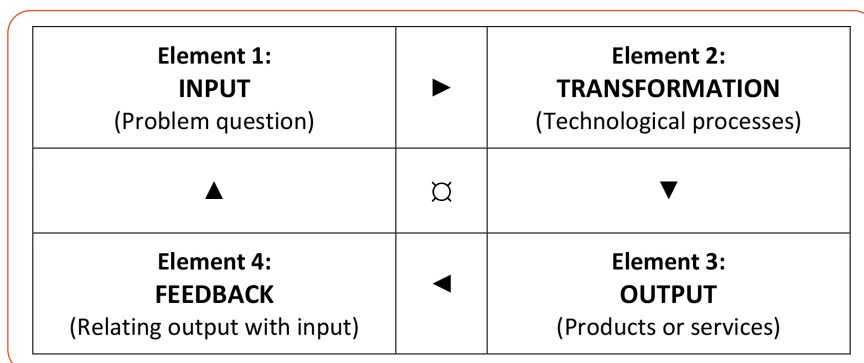


Figure 2. The four basic problem-solving elements of the systems theory: coordinated cyclical route from input to feedback.

PV bleeding, but rarely indicate palpable mass (Figure 1), namely, 10% in this study. This finding is in keeping with other comparable studies.^[16] When three indications (i.e., lower abdominal pain, amenorrhea, and PV bleeding) were present, the clinical question on 50% occasions was confirmed by ultrasonography. This assertion is in keeping with a United States of America (USA) study.^[16]

• Clinical information on sonographic requisition form (SRF)

With particular reference to Table 3, clinical information on SRFs for EP sonography can be deemed inadequate. For example, only 6% of the sample had laboratory pregnancy examinations tests. This finding is in accord with the literature in terms of inadequacies in such tests. In a study conducted in the USA 8.7% of 6055 women diagnosed with EP had pregnancy tests:^[16] an underutilisation of laboratory services in EP diagnosis.

It has been argued that only about 46% of the ultrasound requests adequately provide the required information.^[16,24] On the other hand it has been emphasised that any diagnostic procedure must sufficiently conform to the mandatory clinical information requirement on the requisition form to accustom the diagnostic practitioners in determining the appropriateness of requested examination and clinical question.^[16] The feedback would then be soundly anchored up to its benefit extending to recommending alternative or supplementary diagnostic imaging in radiology where necessary.

• Sonographic report criteria

The responsibility of a sonographer is to generate and compile annotated images as evidence and prepare a written diagnostic report. These competencies must meet verifiable standard towards the clinical audit quality control.^[21] In this study the common standard for EP^[26] embraced empty uterus, adnexal mass/gestation sac and free fluid collection in the Pouch of Douglas notwithstanding a rare version of EP termed heterotopic pregnancy, with coexisting uterine pregnancy. In the sample (n=50) 28% with fairly adequate clinical information for EP, had other sonographic conclusions rather than EPs: namely, normal pregnancies, ovarian cyst, pelvic inflammatory disease (PID), ascites, and normal pelvic sonography without pregnancy. Below average or fairly adequate attainment of requisition information may be seen as reducing the chances of a clinical question matching the diagnostic ultrasound conclusion, while above average data improves the prospects of compatibility between a clinical question and diagnostic sonographic conclusion.

Adequacy of the SRF enables appropriate imaging and decision-making, and application of competencies. For example, at less than 5 weeks' gestation age there is limited sonographic evidence for EP, especially by transabdominal sonography and an inexperienced practitioner: EP evidences may hardly be appreciated.^[5] In this study one ul-

trasound report recorded undefined ovarian cyst, subject to characterising such a cyst; while a follow-up sonography four hours later under higher competencies established EP.

• Relationship of clinical indications to sonographic findings

The relationship between clinical information and sonographic findings is addressed as feedback at the conclusion of sonographic reports. With the availability of adequate key indications for EP on the SRF, suggestive of adequate clinical assessment, the sonographic findings tended to be positive for EP. In this regard, a sonographic examination is desirably positioned as a confirmatory tool (Table 5) in keeping with other studies.^[26,27]

The beta-human chorionic gonadotropin (hCG) values reliably aids diagnosis of EP on a sonographically empty uterus.^[5,7] In this study those with positive beta-hCG laboratory test, in addition to the other indications of EP (e.g., lower abdominal pain, amenorrhea, pelvic mass and PV bleeding) had EP confirmed by ultrasonography. This study is in accord with the literature that emphasises the relationships, comparable to other empirical relationships^[28,29] between preliminary information and sonographic findings in the diagnosis of EP. This observation calls for consistent promotion of quality ultrasonography. Diagnostic reports must be supported by the clinicians' input as a professional trend to be continually promote and amalgamate standard operating procedures (SOPs).

CONCLUSION AND RECOMMENDATIONS

Inadequate information was identified in many sonographic requests for EPs. The relationship between the clinical data and diagnostic reports could improve diagnostic accuracy. The differences among the initially presented number for EPs (100%), sonographically determined (30%), and surgery confirmed (32%) raise questions on the extent of exhaustive clinical considerations to aid adequate information towards diagnostic ultrasonography.

The findings of this study may be seen as significant in establishing the quality of the relationship between the clinicians' provisional diagnosis for EP and the ultrasonographers' conclusion in sonographic reports. The findings would be useful in designing protocol for early detection of EPs based on consensus among involved practitioners. Three recommendations are presented:

1. Ultrasonographers and clinicians should establish compulsory requirements in the design and execution of requests for EP ultrasonography, encompassing inter-relationships between the clinical information and diagnostic feedback.
2. Establish means of communication between the clinicians and the sonographers when the sonographic request or report is inadequate.
3. In-house professional practice consultation protocols to

consistently bring about timely and reliable diagnoses of EPs.

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CONFLICT OF INTEREST

The authors affirm that there are no conflicting interests in this work.

CONTRIBUTIONS OF EACH AUTHOR

MF (Evelyn Hone College) Methodology design, data analysis, reporting format, and proofreading of manuscript; MM (Kitwe Teaching Hospital) literature review, data collection and illustration; BM (St Francis' Central Hospital) abstract preparation, literature revision, and aligning the manuscript to journal requirements. BM and LB (EHC) initial drafting of manuscript.

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