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Thematic Article

Operative Management of Chronic Anal Fissure; Looking for Up to Date Evidence

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Received: June 18, 2020; **Published:** July 06, 2020

Abstract

Among health care professionals, the requirement to base clinical decisions on the best available evidence is recently gaining popularity. Evidence based medicine (EBM) is a conscientious, explicit and judicious use of current best evidence in making decisions regarding the care of individual patients. It is systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values. This paper employs the use of the five step EBM model to formulate an answerable clinical questions; searched for evidence; critically appraised evidence, applied the evidence and evaluated performance in the surgical management of posterior midline chronic anal fissure in a resource limited primary care setting in western Nigeria.

Keywords: *Evidence Based Medicine; Current Best Evidence; Five Step EBM Model; Chronic Anal Fissure*

In a recent clinical encounter in a low resource primary care setting in western Nigeria, a 47-year old man presented with pain in the anus for 7 months. Clinical evaluation revealed a diagnosis of posterior midline chronic anal fissure. He had experienced a harrowing physical, emotional, economic and psychosocial experience before presentation.

Anal fissure is a tear in the epithelial lining of the anal canal [1]. Anal fissure is one of the most common and painful anorectal disorder [2]. The physical and psychological pain emanating from chronic anal fissure is grossly disproportionate to the small size of the anal lesion. In addition to preponderance of pain in most patients, other presentations include bleeding during defecation and constipation [3]. Aetiological factors identified with anal fissure include passage of hard stools, internal anal sphincter hypertonia and relative ischaemia in the posterior midline aspect of the anus where fissure commonly occur [4].

In literature, controversies surround the choice of treatment for chronic anal fissures [1-3]. Its treatment has long been discussed and several different therapeutic options have been proposed [2]. Whatever the modality of treatment, the principle is based on breaking the cycle of pain, muscle spasm and ischaemia [5].

The management modalities for chronic anal fissure ranges from conservative medical approaches to a variety of surgical interventions. Conservative management may fail to produce satisfactory results. When this happens, surgery is indicated. There are advantages and disadvantages associated with the available surgical options.

The two widely performed surgical procedures include Lord's anal dilatation (LAD) and Lateral internal sphincterotomy (LIS) [1-5]. LAD is ancient, safe, simpler to perform, economic and efficacious [5]. This is the preferable option in this context. On the other hand, LIS

in current practice is the preferred gold standard of care for chronic anal fissure [8]. The proposal to abandon LAD as a modality of treatment has been suggested in a systematic review and meta-analysis of studies on treatment of fissure in ano [6]. This recommendation is threatened because in the sub analysis of studies comparing LAD and LIS, power of included studies were low because of small sample size. In addition, the quality of evidence was low because of high risk of detection bias and the results were imprecise because of wide confidence intervals. Evidences in literature differ widely (in different clinical settings) on the relative incidence of recurrence and flatus/faecal incontinence between the two surgical modalities [1,5,8]. The debate is ongoing on the best modality for the treatment for anal fissure.

Based on this lack of consensus, the author sought to find an up to date evidence on which one of the two surgical modalities will be beneficial to this patient in this context. In arriving at this decision, the principles of evidence based medicine were utilized.

Evidence based medicine (EBM) is a systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values.

Evidence-based medicine (EBM) refers to the conscientious, explicit, and judicious use of current best evidence in making appropriate clinical decisions [9]. Hence, it is necessary in EBM to connect the best external evidence with the values and preferences of patients and the expertise and insight of clinicians.

EBM encompasses the use of the results of systematic, reproducible, unbiased research as much as possible in clinical practice, as well as the implementation of patient-centered diagnosis and treatment on the basis of evidence, rather than diagnosis and treatment dependent solely on the judgment of medical doctors [10].

The concept of EBM involves five steps: formulation of answerable clinical questions; searching for evidence; critical appraisal; applicability of evidence; evaluation of performance.

EBM recognises that the research literature is constantly changing [11]. What the evidence points to as the best method of practice today may change next month or next year. The task of staying current, although never easy, is made much simpler by incorporating the tools of EBM such as the ability to track down and critically appraise evidence and incorporate it into everyday clinical practice. Searching for current best evidence is vital. Randomized controlled trials provide best evidence for interventions [11].

Availability of current best evidence engenders improvement in quality of care. Health care model beneficial to the patient are adopted and those with those with relative harm are discarded [11]. This paradigm of incorporating sound scientific evidence into practice requires an attitude of open mind and informed flexibility among clinicians.

Five general steps in the EBM model

The recommended five general steps of EBM applicable a variety of clinical settings are as follows [12]:

1) Generate clinical question

2) Find best evidence

3) Critical appraisal of evidence for validity and usefulness

4) Application of evidence results in clinical practice

5) Evaluation of information, skill, and EBM procedures.

Step 1: Generation of an answerable clinical question

This is the first and most important step in EBM. An important challenge in this step is to formulate an unanswerable clinical question [13].

To overcome this challenge, a good question should have the following attributes [14]:

- Relevant and specific.
- Distinctly communicated.
- Clear in the objective and necessity of inquiry.
- One that will reduce the time required to obtain the answer.

Considering these points, it is recommended that a good clinical question should have four (or sometimes three) essential components:

- The patient or problem in question.
- The intervention, test, or exposure of interest.
- Comparison interventions (if relevant).
- The outcome, or outcomes, of interest.

Thus, an answerable clinical question should be structured in the PICO (Patient or Problem, Intervention, Comparison, Outcome/s) or PIO (Patient or Problem, Intervention, Outcome/s) format.

To illustrate the concept of PICO/PIO with the 47-year old male with the diagnosis of chronic anal fissure, we sought to find the best current evidence for the choice of surgical intervention beneficial to him. In this instance we wished to choose between Lord's anal dilatation (LAD) and lateral internal sphincterotomy (LIS). We desired for a choice of simple surgical procedure in a peripheral hospital setting with good result and relatively lower recurrence rate and complications (flatus/faecal incontinence). We did not want to disregard the effect of complications on the patient on the altar of simplicity and convenience.

The key components of our clinical question were:

- Patient or problem: 47-year old man with chronic anal fissure.
- Intervention: Lords anal dilatation.
- Comparison: Lateral internal sphincterotomy.
- Outcomes: clinical cure, complications.

A four part clinical question was be formulated as follows: In a 47-year old man with chronic anal fissure, does the Lord's anal dilatation offer clinical cure with reduced risk of complications when compared with lateral internal sphincterotomy?

This clinical question was categorized as intervention. We therefore planned to search for a randomized controlled study or systematic literature review of randomized controlled studies to provide information to answer the clinical question. It is important to note that

other categories of PICO based answerable clinical questions will require other types of study designs apart from the one used. Other common categories include questions on diagnosis, prognosis and risk (factors). If a clinical question belongs to the category of diagnosis, the optimal research design to answer the question is not a randomized controlled trial but a cross-sectional study or a case-control study. If a clinical question belongs to the category of prognosis, a cohort study is effective because a follow-up study of patients who have been evaluated from the early stage of a disease is necessary. If a clinical question belongs to the category of risk (factors), a randomized controlled study, a cohort study, or a case-control study is necessary [14].

Depending on the type of information, study design is added to PICO to constitute PICO-SD, which clearly describes the distinct establishment of a study question.

Step 2: Finding the evidence

To search for evidence to answer the research question, we searched online electronic bibliographic databases, which allow thousands of articles to be searched in a relatively short period of time in an increasing number of journals. The ability to search these databases effectively is an important aspect of EBM.

We are aware that the evidence to be retrieved for this purpose be attainable, obtained externally from research or from an expert, up-to-date, timely, of high quality, applicable to individual patients, and appropriately the best [15].

We have the option of choosing form numerous online databases available. These include the Cochrane Library databases, MEDLINE, EMBASE, Google scholar and CINAHL. We decided to conduct our search in three of these bibliographic databases that we are familiar with: MEDLINE, Cochrane library and Google scholar. These are probably the most widely used databases for searching the biomedical literature [16]. They are freely available on the internet, updated regularly and relatively user friendly.

While planning for biomedical literature search in these databases, we generated search terms from the clinical question as follows: Anal fissure, fissure - in - ano, anal tear (problem P), Lord's anal dilatation, manual anal dilatation, anal stretch (intervention I), lateral internal sphincterotomy (comparison C), clinical cure, complications (outcome O), randomized controlled trials, clinical trials (study design SD).

Conducting the search

We commenced the search in MEDLINE (PUBMED) using the generated terms and keywords 11 April 2020. We made use of the Boolean operators "AND" and "OR" [17] to combine individual words or terms. We used AND to retrieve articles containing all terms, while OR was used to retrieve articles containing either term.

Our search strategy in MEDLINE is as shown below:

- (1): Anal fissure OR fissure - in - ano OR anal tear
- (2): Lord's anal dilatation OR manual anal dilatation OR anal stretch
- (3): lateral internal sphincterotomy
- (4): randomized controlled trials OR clinical trials
- (5): (1) AND (2) AND (3) AND (4).

We retrieved 9 articles. Following the review of titles and summary texts, four articles were found to be relevant. The titles and abstracts of these four article were downloaded for appraisal. The most recent of these article was seven years. We did not make use of these articles because we needed best current evidence of at least two years (2018 to date). We then searched the Cochrane database. There was no article retrieved as we limited the search to two years also. We then searched Google scholar also with two - year limitation. We had 77 results out of which two were adjudged relevant. One of the article was a randomized controlled trial and the other was an observational study:

1. Pandit RK, Jha VK. Lateral internal sphincterotomy versus anal dilatation in chronic anal fissure -an observational study. Int J Health Sci Res. 2019; 9(10):105-110.

2. Hareesh GSR, Somangurthy P. Comparative study of manual anal dilatation and lateral internal anal sphincterotomy in the treatment of acute anal fissure. Int Surg J. 2019;6:2022-7. DOI: 10.18203/2349-2902.isj20192359.

We chose the randomized controlled trial for appraisal. The full article was downloaded.

Step 3: Appraising the evidence

We appraised this research evidence for its validity, importance and clinical usefulness to the patient. importance, and applicability to the patient or patients of interest. Critical appraisal provides a structured but simple method for assessing research evidence in all three areas [18]. Several tools for appraising research articles are available. The Chalmers scale and the Jadad scale make use of the scoring system [14]. The checklist system was developed by the Scottish Intercollegiate Guidelines Network (SIGN). The Risk of Bias Assessment tool for Nonrandomized Studies (RoBANS)/and the Risk of Bias tool were developed by Cochrane's group. Others are Newcastle-Ottawa scale, the Deeks criteria and MINORS [14].

We employed the Cochrane's Risk of Bias tool for the critical appraisal of the evidence provided by the selected randomized controlled study. The determination of the level of evidence reflects the quality of the paper. This affects the strength of recommendation put forward by the authors [14]. Appraisal of the quality of literature enables decisions to be made regarding whether to accept the conclusions drawn by the literature or not.

Table 1 shows the items included in the Risk of Bias tool developed by Cochrane's group to appraise the quality of randomized controlled studies. While the tool has simplified the items, it has also reduced the possibility of subjective and arbitrary answers to the same items as well as the possibility of lowered reliability depending on the appraiser's understanding and skillfulness with respect to the methodology.

In addition, the Risk of Bias tool is easy to use because it provides specific descriptions and guidelines for each item to select from one among "high risk of bias, No," "low risk of bias, Yes," and "uncertain risk of bias, unclear" depending on the information included in the literature [19].

Understanding risk of bias assessment

The quality of literature is represented by the risk of bias. Error is measurement deviating from the truth. Error can be random (inconsistent) or systematic (has direction). Systematic error, also called bias, is related to research procedure while random error is generated regardless of the research procedure or method. Bias is classified as selection bias when it is related so sampling and information bias when related to exposure or outcome measurements. The third type of bias is confounding. In confounding, the relationship between the exposure and the outcome is confused by the effect of something else, called the confounder [14].

Item	Author's judgement
Random sequence generation Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.	Yes No Unclear
Allocation concealment Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	Yes No Unclear
Blinding of participants and personnel Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Yes No Unclear
Blinding of outcome assessment Detection bias due to knowledge of the allocated interventions by outcome assessors.	Yes No Unclear
Incomplete outcome data Attrition bias due to amount, nature, or handling of incomplete outcome data.	Yes No Unclear
Selective reporting Reporting bias due to selective outcome reporting.	Yes No Unclear
Other bias due to problems not covered elsewhere in the table. □ Yes □ No □ Unclear	Yes No Unclear

Table 1: *Risk of bias [19].*

With the presence of bias in a study, the results will be erroneous (overestimation or underestimation of effect sizes). Therefore, a study methodology should be strictly applied to minimize the risk of bias [20].

Assessment of risk of bias for the selected study as a quality appraisal process

A study of high quality will be assessed to have a low risk of bias.

Random sequence generation: No selection bias because "Patients were randomly assigned to either group; randomization was done by computer generated random table".

Allocation concealment: No selection bias because there was concealment of allocation before surgery. The computer generated random allocation did not allow researchers to what type of intervention the next participant would have.

Blinding of participants and personnel: There was risk of performance bias because the researchers had knowledge of the intervention during surgical intervention.

Blinding of outcome assessment: There was risk of detection bias because the researchers had knowledge of the intervention when assessing the study outcomes.

Incomplete outcome data: There was no risk of attrition bias because all participants were accounted for.

Overall the risk of bias for this study was moderate, and thus the article is of moderate quality.

What are the results? Are the results precise?

Effect size and precision; From the study database, the authors found out that at 24 hours post operatively, the odds of pain scores in the LAD arm is about five times more than the odds of pain scores in the LIS arm. This relationship is statistically significant although not precise because of the wide 95% confidence interval (OR 5.50 95% CI 1.46 - 20.76). Subsequent follow up of the differences in pain scores between the two groups before discharge, 1 month, 3 month and 6 months were not statistically significant (p value- 0.1390, 0.6186, 0.4665 respectively).

In addition, data analysis did not show statistically significant difference in episodes of post - operative bleeding between the two groups at 24 hours, before discharge, 1st month, 3rd month and 6th month (P values > 0.05). There was also no statistically significant difference in mucous discharge before discharge and at one month (p values > 0.05). Relating to incontinence, a small fraction (3 in LAD group and 2 in LIS group) had this problem lasting 3 - 4 days and resolving with intervention. Post-operative hospital stay in LAD group is comparable to LIS group (minimum 3 and maximum 5 days).

After three months of treatment, the difference in wound healing between the two groups was statistically not significant (p value 0.565, OR 2.04, 95% CI 0.18 - 23.27). Recurrence rate between the two groups was also not statistically significant (1/40 vs 2/40, p value 0.57).

The authors concluded that there were minor differences in pain, comparable period of hospital stay, cure rate and complications between LAD and LIS We therefore decided that this LAD is suitable for our patient. LAD is less invasive than LIS with equivalent efficacy and safety.

Step 4: Applying the evidence

The patient was appropriately prepared for surgery following written informed consent.

Surgical procedure

Second generation cephalosporin and metronidazole were administered before surgery as prophylactic antibiotics in stat doses. The procedure was carried out under general anaesthesia with patient in lithotomy position. After cleaning of the surgical field with Povidone-iodine, draping of the field was done.

Anal dilatation was performed as described by Watts., *et al*. [10] First digital rectal examination was performed to confirm clinical findings and to rule out other morbidities. Thereafter fully lubricated index finger of right hand was introduced, and constriction band was palpated which corresponds to anorectal line. After palpating the constriction band, fully lubricated index finger of each hand (one after the other) was introduced in the anal canal and continuous gentle outward pressure was applied, till the constriction overcame. During this procedure hand repeatedly moved all around in order to relax all the segment. When the anus was relaxed enough, two other fingers were inserted from each hand without much force. The four fingers in the anus were left for four minutes and then withdrawn.

Post-operatively patient was given oral second-generation cephalosporin and metronidazole for three days and make it oral tablets while discharge for one week. Injectable NSAIDs were administered the following evening and oral NSAIDs were started from the next day. Patients resumed eating after six hours of surgery. Sitz bath and laxatives were advised from the first postoperative day and continued for one week. Patients were discharged on third post-operative day.

Step 5: Evaluating performance

The patients was followed up to assess any complications of the procedure (pain, incontinence, abscess formation, hematoma, recurrence). The follow up schedule was two weeks, one month, three months and six months. The patient was advised to contact the hospital on telephone if necessary.

The patient experienced slight blood smear during defecation that stopped without intervention within the first two weeks post operatively. He also has transient incontinence that resolved spontaneously during this period. The anal wound had also healed completely at about six weeks.

Conclusion

In this paper, we elaborated on the use of EBM for clinical decision making relating to choice of surgical intervention for the treatment of chronic anal fissure. This decision was based the five step EBM model. We integrated best available evidence with our clinical preference and patient's context.

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Volume 4 Issue 8 August 2020