Background Evidence-based medicine (EBM) is the conscientious and judicious use of the best data in the literature for optimal care of patients. This must go through four steps: (1) formulation of a clear clinical question, (2) research documented facts, (3) analysis of results and (4) application of results in clinical practice.

Methods Our choice of application was gallstones and complications because it is a frequent and complex pathology that requires several clinical questions. The experimental design was considered to be a non-comparative cohort study (patients were exposed to evidence-based medicine). It can also be considered as a feasibility study. In our application we took the following steps: (1) formulation of several clinical questions, (2) literature search in medline using MeSH and Cochrane library, (3) analysis of results through critical reading of collected articles, (4) calculation of percentage of patients for each clinical situation and correlating it with the levels of evidence. Then we estimated the matching of our application with EBM by calculating the number of positive responses.

Conclusion As a conclusion we were able to apply EBM with some degrees of confidence. However, some limitations related to environmental factors are still present. We can overcome this problem by introducing an educational learning model.

KEYWORDS evidence-based medicine, gallstones, non-comparative, cohort, education

INTRODUCTION

Often, clinicians tend to base their decisions on fragile foundations. In evidence-based medicine (EBM), we rather speak of low levels of evidence. A recent Canadian study found that while 81% of doctors visit at least once a week a colleague or a consultant to make a decision, only 28% use an original article in the same period.

If no one thinks to question the importance of experience in clinical practice, we must nevertheless recognise its limitations. The medical dictionary of sceptical defines the experience as follows: "the same mistakes with increasing confidence along many years".

EBM has been defined in 1996 by Sir David Sackett (McMaster University): "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making about the care of individual patients".

The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

The clinical evidence was rated according to the assessment system of the Infectious Disease Society of America:

- Level I: Evidence from at least one properly designed randomised controlled trial or meta-analysis.
- Level II: Evidence from at least one well-designed clinical trial without proper randomisation, from cohort or case-controlled analytic studies (preferably from one centre), from multiple time-series or from dramatic results in uncontrolled experiments.
- Level III: Evidence from opinions of respected authorities on the basis of clinical

Biliary colic occurs when the gallbladder contracts against a stone which is transiently obstructing the cystic duct. Patients with biliary colic complain of sharp, intermittent, cramping right upper quadrant pain, pain radiating to the right shoulder, nausea and vomiting. The pain occurs most commonly after a fatty meal and may last for several hours; complain of unresolving...
right upper quadrant pain, nausea, vomiting, anorexia and fever. Leukocytosis is common, while alkaline phosphatase and bilirubin are typically normal.

Acute cholecystitis occurs when the cystic duct becomes obstructed by a gallstone, leading to gallbladder distention, serosal edema, mucosal sloughing, venous and lymphatic congestion, and ischemia. Patients with acute cholecystitis complain of unresolving right upper quadrant pain, nausea, vomiting, anorexia and fever. Leukocytosis is common, while alkaline phosphatase and bilirubin are typically normal.

MATERIALS AND METHODS

This is a prospective and longitudinal study that took place during the years 2007, 2008 and 2009. The single-blind study poses no ethical problem because the patient is not aware that it will be handled in accordance with a specific reasoning. In fact, each patient underwent a targeted literature search leading to an assessment with levels of evidence. Randomisation was done by coin launching. The number of cases studied was limited to 150. The age of the patients was between 24 and 75 years. Our method was to apply the various stages of EBM. We tried to reproduce the mode doing that is the most difficult step. This application has been treated as an observational feasibility study or an uncontrolled cohort with a limited number of patients (usually this kind of study requires a large number of cases).

In the case of this study, the group of patients ‘exposed’ to EBM (such as smoking or exposure to radiation) is followed in a prospective manner on two axes:

1. The first three steps (question, information, analysis)
2. Results in the management of patients

Finally, we report the percentage of patients who have ‘joined’ to EBM and those who did not. From another angle it is also the percentage of physicians who have followed this approach.

No statistical analysis was required because this is an observational study. The observation period was set to 2 years from the last practice. We began monitoring the following stages from 150 patient records:

Formulation of a clear clinical question

The first point was to make special presentation folders patients including ‘educational prescription’ which is the formulation of a clear clinical question (first step of EBM). This record included 33 items for each patient and allowed from a comprehensive examination, a thorough clinical examination and appropriate complementary examinations to formulate the right questions based on the criteria, PICO (Patient Intervention Comparison Outcome).

The selected questions were:

1. Is cholelithiasis correlated with BMI (body mass index)?
2. Is cholelithiasis related to genre?
3. Is ultrasound the best screening of gallstones?
4. What is the sensitivity and specificity of CT scan for gallstones?
5. Is preoperative cholangiography systematic?
6. Is the intraoperative cholangiography mandatory in laparoscopy?
7. Should we operate acute cholecystitis in emergency or after treatment?
8. What is the best surgical approach to gallstone (laparotomy, laparoscopy)?
9. What is the best surgical approach to acute cholecystitis?
10. Should we use surgery at the first biliary colic?
11. What are the advantages and inconveniences of endoscopic treatment for common bile duct stones?
12. What are the risks of laparoscopy?
13. Does the number of laparoscopic trocars affect the management?
14. What is the best drainage of the common bile duct after choledochotomy?
15. Is the drainage of the peritoneal cavity mandatory after a cholecystectomy?
16. Is histopathological examination systematic after cholecystectomy for gallstones?
17. What is the management before the intraoperative discovery of stones in the common bile duct during cholecystectomy?

Literature or research documented facts

We used the two most appropriate databases namely MEDLINE (PubMed) and the Cochrane Library databases.

Critical reading

We had chosen papers that answered the questions listed above and according to the following criteria: availability, relevance, updating and indexing. Therefore, among the issues already mentioned we have learned a few (see results). Our critical reading was inspired from different methods.

RESULTS

Distribution by BMI: between 24 and 33 (69%), less than 24 (31%).

Distribution by genre: women 77%, men 23% (Fig. 1).

![Fig. 1 Genre and body mass index repartition.](image)
Evidence-based medicine in biliary surgery

Ultrasonography was performed in 74% and 20.66% in lithiasis of the common bile duct was detected. Intraoperative cholangiography (IOC) was performed in 27.33%; 17.7% of cholecystitis were made within days of hospitalization. Laparoscopic cholecystectomy (LC) was performed in 41% of cases.

In the case of stones in the common bile duct, Kehr drain was used in 90.33%, endoscopic treatment was attempted in 12.90%. After surgery on the gallbladder, drainage of the abdominal cavity was performed in 68% and histological examination was asked in all cases (Fig. 2).

For the monitoring of patients, we had 24 complications including 17 wound infection (11%), 6 residual common bile duct stones (4%) and an incisional hernia (1%) (Fig. 3).

The results shown above are given as a percentage of patients who responded to questions of the materials and methods section. We want to correlate these results with levels of evidence. So, we have chosen empirically the following correspondence scale:
Level III: <33%; Level II: 33%–66%; Level I: >66%

DISCUSSION

We adapted our discussion and analysis of graphs according to PICO criteria:
1. Gender: there is a predominance of female sex: 77% vs. 23%. This means that the biliary disease is much more common in women. However, no study has found the reason.
2. BMI: 69% of patients had a BMI between 24 and 33. This indicates a relationship between obesity and biliary pathology. Once again there is no evidence.
3. Ultrasonography: It is the most helpful diagnostic test for biliary pathology (Evidence grade I). In our case it was practiced in 74%. So our clinical practice is consistent with EBM.
4. Laparoscopic cholecystectomy: (Evidence grade I). In our study it was practiced in 41%. This is an insufficient percentage adherence to EBM. This can be justified by the refuse of the patient or a difficult clinical situation or the experience of the surgeon.
5. Intraoperative cholangiography: There is no robust evidence to support or abandon the use of IOC. Level 1 evidence for IOC is of poor to moderate quality. None of the trials, alone or in combination, was sufficiently powered to demonstrate a benefit of IOC. Further, small trials cannot be recommended. In our study, 72.33% of operated patients had IOC. This result is weakly in accordance with EBM. It is due to the learning curve and the lack of experience of young surgeons.
6. Early cholecystectomy for cholecystitis: Patients with acute cholecystitis should undergo cholecystectomy within 72 hours of admission. (Evidence grade I)\(^6\). In our experience we obtained 17.70% which is a low number for adhesion to EBM. This is due to lack of technical facilities and usual practices of surgeons.

7. Common bile duct stones: Trans-abdominal ultrasound scanning ( USS) is recommended as a preliminary investigation for CBDS and can help identify patients who have a high likelihood of ductal stones. However, clinicians should not consider it a sensitive test for this condition (Evidence grade III)\(^1\). In our application, all patients who underwent an ultrasound at a biliary colic, a CBDS was found in 20.66%. This value is consistent with the EBM.

8. CBDS T-tube drainage: Studies comparing primary closure versus T-tube drainage suggest similar rates of complications with shorter operating times and a trend toward shorter hospital stay with primary closure (Level II)\(^13\). In our study the open bile duct was addressed with closure over a T-tube in 90.33%. This percentage is greater than the level of evidence because of special conditions and requirements such as inflammation of CBD, postoperative radiographic evaluation of the biliary system, extraction of retained stones and control of biliary fistula.

9. CBDS: ERCP and biliary sphincterotomy: Biliary sphincterotomy followed by stone extraction using a basket or balloon catheter represents standard endoscopic therapy for CBDS (Evidence grade I)\(^14\). In our case only 12.9 % of patients had ERCP which is a low number compared to Level I evidence.

10. Abdominal drainage: Drains are not needed after elective laparoscopic cholecystectomy and their use may increase complication rates (Level I, Grade A)\(^10\). In our case 68% of operated patients had abdominal drainage. So EBM is not respected. This is due to particular clinical situation such as cholecystitis, gallbladder break and poor control of bleeding. This is also due to certain habits of clinicians. It should be noted that the majority of interventions for gallstones are performed by junior surgeons who placed in the majority of cases an abdominal drain because of lack of experience and confidence.

11. Histopathological analysis: The histopathological spectrum of gallbladder after cholecystectomy is extremely variable. Incidental diagnosis of carcinoma gallbladder is not rare. Siddiqui et al. discovered evidence of malignancy in 6 (2.8%) cases on subsequent histopathological examination of gallbladder specimen, which showed no gross features of cancer. These cases had neither symptoms suggestive of underlying malignancy nor was cancer reported on any of the reoperative investigations. They strongly advocate routine histopathology of all cholecystectomy specimens. Old patients and patients having long duration symptoms are strong candidates for histopathology of gallbladder specimen\(^14\). González et al. think that in almost half (46%) of the extracted gallbladders it would be safe not to send the specimen to the pathology unit without compromising patient safety. They have shown a simple and non-expensive method for selecting gallbladders that must be sent to the pathology department. Nevertheless, they believe that further studies with a greater number of cases are necessary to confirm this hypothesis\(^15\). We applied anatomopathological analysis systematically (100%). We noted that our evidence-based approach has been biased by a contradictory expert opinion approach. This puts us in a situation of inability to answer question 16.

12. Post operative complications:
   a. Wound infection: Laparoscopic cholecystectomy (LC) is associated with a lower risk of wound sepsis than open cholecystectomy. Antibiotic prophylaxis in LC is not only unnecessary but also increases the overall cost of surgery and hospitalisation. It is important to follow the guidelines for antibiotic prophylaxis for cholecystectomy in coordination with the hospital infection control policy. This will result in a more appropriate use of the prophylactic agents\(^16\) (Evidence grade III). In our study, wound infection was noted in 11% of cases. We administered these infections by probabilistic anti biotherapy and dressings twice daily.
   b. Residual common bile duct stones: Biliary sphincterotomy and endoscopic stone extraction (ESE) is recommended as the primary form of treatment for patients with CBDS post-cholecystectomy (Evidence grade III)\(^11\). In our series, ERCP was performed on all patients, indicating a very good application of EBM in this case. This is mainly due to the availability of technical equipment and patient consent.
   c. Incisional hernia: Patients who presented an incisional hernia underwent cholecystectomy by laparotomy. Hernia repair is based on the use of synthetic and permanent mesh\(^17\) (Evidence grade III). In our case, 1% of patients had incisional hernia it was consistent with guidelines.

In conclusion, our experimental application of EBM in gallbladder diseases is acceptable since we had six clinical situations in accordance (3. 5. 7. . 12.a 12.b. 12 c.) versus five (4. 6. 9. 8. 10 11.).

CONCLUSION

Physicians in the coming decades will face a very powerful technology that respects the rules of computer-aided medical decision making. Among the new concepts EBM is a paradigm of medical reasoning and care of patients. A question is always asked: Are we facing a new fad that will revolutionise medicine and will progress at the same speed as TICs (Technologies of Information and Communication). Ten of the top 40 global experts believe that the next 10 years will be marked by the Association of Internet and Health (IEEE Spectrum).
Currently, EBM is a method that is thriving even though it raises many thoughts and criticism from the medical community.

However, practical applications are still limited especially in surgery. Hence the present work can be likened to a model that we present to physicians.

Indeed we propose a simple method to estimate the applicability of EBM in surgical pathology. We propose a scale to assess patient compliance to EBM. This three-level scale is used to correlate the number of patients to a percentage of response to guidelines and this for each of the identified questions. So, how to get a single representative value for the biliary disease? Should we make an intuitive summation of resulting percentages, or give each question a specific weight.

It is however possible to evaluate another way of recommendations applicability by a variable weighting of the three axes of EBM (documentary research, clinical status and patient values) for each question.

According to our results, we have not been able to follow perfectly the logic EBM. This is due to several factors including: the failure to build a factual thinking within our hospitals and our universities and the difficult transition from experience-based medicine to EBM. At this point, comes the importance of teaching EBM at all levels of medical studies18.

However, EBM could disrupt clinical judgment, in so far as the search for evidence over rides the ability of physician decision. This results in a significant number of clinical action protocols that potentially remove any initiative to physicians and nursing staff.

REFERENCES