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Decision-Making in Patients with Gallstones: Development of a Clinical Algorithm Using the Instrument of a Consensus Development Conference

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Abstract
Since decision-making in patients with gallstone disease is a very common medical problem, a carefully planned consensus development conference was held to develop a clinical algorithm using an electronically transmitted group response of the panel and the general audience. Only symptomatic patients are candidates for treatment. Minimal diagnostic requirements are ultrasound, determination of leukocytes, alkaline phosphatase and bilirubin in the blood, and preoperative intravenous cholangiography. Detected common duct stones should nowadays be removed by endoscopic retrograde cholangiopancreatography. Symptomatic gallbladder stones are managed by laparascopic cholecystectomy as the new standard treatment. Conventional cholecystectomy should be done in patients with liver cirrhosis and portal hypertension, suspicion of cancer, certain cases of severe, acute or chronic inflammation, severe adhesions in the upper abdomen and pregnancy. Medical stone dissolution and extracorporeal shock-wave lithotripsy should be restricted to a small group of patients with a high surgical risk and who have small, roentgen-negative stones and a patent gallbladder.

Introduction

The worldwide explosion in information, technical equipment, and costs for medical care has made mandatory quality assurance and audit programs a vital challenge for national and international health care systems [1].

At first glance, results from randomized controlled clinical trials, as the highest standard of scientific objectivity, seem to be the main stream for defining standards. However, they answer too few questions in the complex flow of clinical decision-making; they are frequently open to methodological criticism and to the general problem of external validity [2], and their results are rarely introduced into direct routine decision-making. Another ex-

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treme for setting standards is the judgment of an outstanding expert who is so powerful in a medical community that almost all its members have to follow his path of decision-making [3]. This situation is very unusual in a democratic society and no longer consistent with the overload of knowledge and technology in our time [4]. Hence other procedures for solving collective decision problems have to be applied to set standards or practice guidelines which fulfill at least two conditions: they must include a formalized way of seeking advice [5], and this way must be acceptable to people working in social sciences to give it a satisfactory degree of scientific validity. Among others two methodologies have been developed or applied in clinical medicine in the last 10 years which fulfill these demands: consensus development conferences [6] and clinical practice guidelines [7]. The first includes a panel of experts and a large number of participants, the latter are collected in a nominal group process [8] by a restricted number of peers.

Since decision-making in patients with gallstones is a very common surgical problem, the Permanent Working Party on Clinical Trials (CAS) has chosen it for an experiment to develop practice guidelines in gallstone disease. This experiment combined the two methodologies: a carefully planned consensus development conference [9], and the production of a clinical algorithm by an electronically transmitted group response of both the members of the panel and the general audience as an element of the Delphi method [5].

Methods and Participants in the Consensus Conference

The course and structure of the conference in Frankfurt followed that of a European model as developed for technology assessment [10]. The five basic processes of such a group consensus development were performed as follows.

Planning Committee

The issue in need of evaluation was identified by the general assembly of the CAS in Munich in November 1990, which also nominated the planning committee. This group, consisting of expert surgeons in particular fields and methodologists for clinical trials, met in Stuttgart in July 1991, and proposed the questions for the meeting, the speakers and the panel.

Panel

The panel in the November conference consisted of speakers who were experts in concepts and methods on standards: G. Carstensen (Mühlheim/Ruhr) for surgery; H.K. Selbman (Tübingen) for statistics and quality assurance, and H.L. Schreiber (Göttingen) for legal sciences. Furthermore, speakers were included who were experts in the treatment of cholelithiasis: O. Boeckl (Salzburg) for conventional, open cholecystectomy; H.D. Becker (Tübingen) for laparoscopic cholecystectomy; W. Rösch (Frankfurt), physician for conservative treatment of gallstones, including chemical litholysis and extracorporeal shock-wave lithotripsy (ESWL), and D. Schröder (Frankfurt) for acute cholecystolithiasis. The panel was completed by general practitioners: H. Hamelmann (Kiel); C. Herfarth (Heidelberg) for surgery, and W. Lorenz (Marburg) for clinical trial methodology.

Questions Defined before the Meeting and Participants of the Auditorium

The planning committee prepared 10 questions prior to the meeting. Before the meeting they were sent to the panel and to a company (Lux AV, W-3505 Lohfelden) which provided the technical equipment for the conference to permit an electronically transmitted group response of all panelists and separately of all members in the auditorium to each of the questions.

The auditorium consisted of 62 participants including 24 surgeons with consultant level, 17 surgeons, 11 surgical trainees and 10 basic scientists.

Conducting the Conference

The meeting lasted for 1 day (November 15, 1991). First, the main reports (20 min) of speakers, who were experts in concepts and methods on standards (see Panel section), were presented. Then the experts in the treatment of cholelithiasis delivered their knowledge and judgement in the same sequences as given in the Panel section. The same discussion time was provided for each of the reports as that for the presentation of each of the papers. After a prolonged pause for an individual exchange of ideas and arguments, special reports (10 min) were presented on the aspects of treatment and prognosis of cholelithiasis, which were regarded as important for developing the clinical algorithm by the planning committee: perioperative risk analysis; respiratory function during both endoscopic and conventional cholecystectomy; release of mediators by stress and injury and postoperative pain and recovery; the measurement of learning by variations of operation time; the preoperative situation of patients in hospitals with different levels of care delivery; the present status of ESWL; minilaparotomy, and special treatment modalities via a surgical rectoscope (for details see a previous report on the methodology [9]).

Finally the clinical algorithm was developed in a 2-hour period by all members of the conference. For this purpose, electronic voting was implemented with a keyboard at each place provided for the audience. Before presentation of the algorithm, the chairman of the conference (H.G. Beger) emphasized that it is absolutely necessary not to lose track of the individual case in connection with the subsequent presentation of the clinical algorithm. Its development for a typical, paradigmatic clinical scenario should not lead to its uncritical and schematic application in individual patients.

The algorithm was presented by the chairman of the planning committee (M.W. Büchler). It had been prepared as a draft by him and the planning committee in its session in July. Each step in the flow diagram (fig. 1) including clinical state boxes, decision boxes and action boxes [11, 12] was discussed. In this regard the 10 questions were formally proposed to the members of the panel and the audience. The answers from the two bodies of the conference were analyzed separately. A single step in the algorithm was accepted if a majority (>50%) of the panel and the audience did not reject it. The final algorithm is included in the consensus statement. It contains all