OPERATIVE CHOLANGIOGRAPHY COST-EFFECTIVENESS — ROUTINE VERSUS SELECTIVE UTILIZATION

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SUMMARY

OPC is widely utilized routinely, as well as temporary drainage of the explored ducts is the most common approach to such ducts, assuming that choledochal calculi migrate from the GB, until proved otherwise. These are, nonetheless, questionable issues. Aiming to define their exact usefulness the Author reviewed his experience, retrospectively (1973-79, OPC routine) and prospectively (1980-82, OPC selective) with primary surgery for lithogenic disease: 308 Cholecystectomies, 85 of which (27,5 %) underwent CBDE. From these, 14 were temporarily drained and 71 definitively decompressed, either abolishing or bypassing the S.O. Two patients died, for an overall mortality rate of 0,64 %. One case (0,3 %) of an unsuspected stone and two anomalies (0,6 %), only detectable by OPC, were picked out by this method. There were no iatrogenic injuries. Over 64 % of duct stones were stasis calculi. The costs were 20 % higher when OPC was routine. The long term POOR results (patients requiring resurgery) were significantly higher among the ducts temporarily drained as opposed to those not meeting the exploration criteria ($^5/_{14}$ or 36 % versus $^4/_{222}$ or 1,8 %, $p = 0{,}001$) and to those explored and definitively decompressed (36 % versus $^0/_{70}$ or 0 %, $p = 0{,}001$). It is suggested that the key problem is a motility disorder of the S.O. (achalasic dysfunction?), the duct stones being a consequence of it, not the pathology itself. The poor cost-effectiveness of routine OPC does not justify it, at least when experienced surgeons are involved. Likewise a permanent decompression of most ducts requiring exploration seems to offer the best long term prognosis.

RESUMO

Rentabilidade da Colangiografia Operatória (COP) de rotina versus selectiva

A rentabilidade da colangiografia operatória (COP) utilizada por rotina, bem como a descompressão temporária das vias biliares por tubo de Kehr, após a sua exploração cirurgica, constituem motivos de controvérsia. Analisando a sua experiência retrospectivamente de Janeiro de 1973 até Dezembro de 1979 (Grupo A, COP rotina, 162 colecistectomias, 44 ou 27 % das quais com exploração simultanea do colédoco) e prospectivamente de Janeiro de 1980 até Dezembro de 1982 (Grupo B, COP selectiva, 146 colecistectomias, 41 ou 28 % com exploração das vias biliares) os Autores sugerem que os cálculos coledócicos devem ser considerados como um sintoma ou consequência de uma disfunção do esfincter de Oddi e não a própria patologia. Nesta conformidade dificilmente se pode justificar a utilização de COP por rotina. Da mesma forma a descompressão definitiva da grande maioria de colédocos necessitando exploração cirúrgica oferece o melhor prognóstico a longo prazo.

INTRODUCTION

Ever since Mirizzi [1] first used it, routine operative cholangiography (OPC) became a widely accepted manoeuver,[2-9] aiming to uncover, otherwise unsuspected, duct stones, to avoid unnecessary explorations or else to serve as a road map of the biliary tree. Likewise, most surgeons believe that, after a common bile duct exploration (CBDE), a temporary, T-tube, drainage of the biliary tree is the procedure of choice, reserving a definitive drainage technique for a very few, specific, situations.[10, 11] Whoever assumes these views as the wisest ones takes for granted that the majority of ductal calculi are, primarily, formed within the gallbladder (GB), supposing, as well, that ridding the duct of them all, while making sure that none is left behind would be just enough since only *forgotten* or *missed* ones would originate further trouble. These are, nevertheless, quite questionable issues.[12-18] Analyzing our experience, retrospectively (Jan. 1973 to Dec. 1979) and prospectively (Jan. 1980 to Dec. 1982), we attempted to seek answers to the following questions: *a*) Are *missed* stones the major source of postcholecystectomy, cholestatic, syndromes or is it, rather, an ill-functioning Sphincter of Oddi (SO) left behind, retaining calculi which would, easily, slip through or else causes bile stasis with stone reformation around any, otherwise innocent, nucleating agent? *b*) How efficient and cost-effective is routine OPC vs. extra-ductal palpation? *c*) How frequent and difficult to detect, by means other than OPC, are true anatomical anomalies of the extra-hepatic biliary tree? *d*) Which is the most effective approach to a common bile duct requiring exploration?

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TABLE 1 **Primary surgery for Biliary Lithiasis and/or associated pathology, with Routine OPC (GROUP A) Jan. 1973 to Dec. 1979**

Operations	Nr.	Operat.* Morbid.	Operat.§ Mortal.	Avge postop. Hospit. days
Cholecystectomy, simple	118	3 (2.5 %)	1 (0.8 %)	7 (5-15)
CBDE, L-L Choledochoduodenostomy	25	3 (12 %)	0	8 (6-25)
CBDE, Choledocholithotomy, T-Tube Drainage	14	0	0	13 (11-20)
CBDE, Sphincteroplasty	5	1 (20 %)	0	13 (12-15)
Total	162	7 (4.3 %)	1 (0.6 %)	9 (5-25)

44 CBDE for: Choledocholithiasis 32 (72.7 %); «Papillary Stenosis» 8 (18 %); Pancreatitis Nodule 2 (4.5 %); Cholangitis 2 (4.5 %).
* Wound Infections 4; Acute Pancreatitis 1; Biliary Fistula 1; Congestive Heart Failure 1.
§ A 40 yrs. old lady dying, suddenly, on the 5th Postop. day, the exact cause of which could not be established at autopsy.

TABLE 2 **Primary surgery for Biliary Lithiasis and/or associated pathology, with Selective OPC (GROUP B) Jan. 80 - Dec. 1982**

Operations	Nr.	Operat.* Morbid.	Operat.§ Mortal.	Avge postop. Hospit. days
Cholecystectomy, simple	105	2 (1.9 %)	0	6 (4-11)
CBDE, L-L Choledochoduodenostomy	36	1 (2.8 %)	1 (2.8 %)	6 (4-12)
CBDE, Roux-Y Hepaticojejunostomy	3	1 (33.3 %)	0	12 (11-13)
CBDE, Sphincteroplasty	2	0	0	11
Total	146	4 (2.7 %)	1 (0.7 %)	7 (4-13)

41 CBDE's for: Choledocholithiasis 29 (70.7 %); «Papill. Stenosis» 9 (22 %) Pancreatitis Nodule 2 (4.9 %); Cholangitis 1 (2.4 %).
* Wound Infections 2; Deep Vein Thrombosis 1; Cholangitis 1.
§ A 74 yrs. old lady, dying on the 7th postop. day, from massive UGI bleeding, and intact stoma being demonstrated during autopsy.

TABLE 3 **Findings associated with patients undergoing Cholecystectomy and Common Bile Duct Exploration (CBDE)**

Preoperative Findings	GROUP A n=44 pts.	GROUP B n=41 pts.	TOTAL n=85 pts.
Upper Abdominal pain, related to meals	42 (95.4 %)	39 (95.1 %)	81 (95.3 %)
History of Jaundice, past or present	41 (91.0 %)	39 (95.1 %)	79 (93.0 %)
History of Fever and Chills, Dark Urine	22 (50.0 %)	20 (48.8 %)	42 (49.4 %)
History of Acute Pancreatitis	3 (6.8 %)	6 (14.6 %)	9 (10.6 %)
Bilirubinemia > 3 mgm/dl	30 (68.2 %)	28 (68.3 %)	58 (68.2 %)
Bilirubinemia > 7 mgm/dl	10 (22.7 %)	10 (24.4 %)	20 (23.5 %)
SGOT, SGPT > twice normal	29 (66.0 %)	26 (63.4 %)	55 (64.7 %)
Alkaline Phosphatase > twice normal	30 (68.2 %)	26 (63.4 %)	56 (65.9 %)
CBD width ≥ 10 mm, as seen on USG, IVC with contrast stasis	40 (91.0 %)	38 (92.7 %)	78 (91.8 %)
Radiologically proven duct stones (USG, IVC or ERCP)	24 (54.5 %)	22 (53.6 %)	46 (54.1 %)
Intraoperative, Pre-Choledochotomy, Findings			
CBD width ≥ 10 mm, as measured by ruler or caliper	43 (97.7 %)	41 (100 %)	84 (98.8 %)
Palpable Stones	31 (70.4 %)	29 (71.0 %)	60 (70.5 %
Multiple, small, GB stones	5 (11.3 %)	3 (07.3 %)	8 (09.4 %)
Pancreatitis Nodule	2 (04.5 %)	1 (02.4 %)	3 (03.5 %)
Intraoperative, Post-Choledochotomy, Findings			
Choledochal Calculi	32 (73.0 %)	29 (71.0 %)	61 (71.7 %)
Biliary Mud, Fibrin Debris	15 (34.0 %)	17 (41.0 %)	32 (37.6 %)
Thickened CBD wall	30 (68.2 %)	30 (73.2 %)	60 (70.6 %)
Duct Stones similar to GB Calculi	6 (13.6 %)	3 (7.3 %)	9 (10.6 %)

PATIENTS, METHODS

Only primary surgical cases are considered in this study. Concomitant, *en passant*, cholecystectomies performed in the course of laparotomies for other pathology are not included. A total of 308 cholecystectomies, constituting GROUPS A (162 patients, Jan. 1973 to Dec. 1979) and B (146 patients, Jan. 1980 to Dec. 1982) form the basis of this study. The patients were well matched as for age and sex in both groups, the female/male ratio being 3/1, the highest incidence occurring during the sixth decade of life. The sex ratio was slightly skewed for the male side among patients undergoing CBDE. Tables 1 and 2 outline pertinent surgical data. The preoperative evaluation, follow-up and criteria for CBDE, as previously described,[17, 18] were similar in both groups, differences residing, solely, on the intraoperative assessment and decision-making processes. The measurement of the CBD width, under next to physiological circunstances, via ultrasonography (USG) and/or intravenous cholangiography (IVC) was a key point. Any duct suspicious of needing an exploration was evaluated by ERCP. Routine OPC was the rule in Group A, 44 patients of which (27 %) met the criteria for duct exploration, a temporary, T-tube, decompression having been carried out in 14 and a permanent one in 30 (Tables 1, 3, 4). In Group B reliance was, primarily, placed upon a thorough, extra-ductal, palpation and inspection, rather than on OPC (Table 4). A wide Kocher manoeuver is mandatory to accomplish this goal with success. In 93 patients of this group (63.7 %) there were no indications for exploration (CBD type A), in 12 (8.2 %) no clear-cut reasons for or against it were met (CBD type B), while absolute criteria for choledochostomy (CBD type C) existed in 41 (28 %). OPC was performed only on type B ducts, the decision being against exploration in all of them, and in four type C ducts, all of which were definitively decompressed (Tables 2, 3, 4), either abolishing or bypassing the SO. As outlined in Table 3 we attempted to define, from all preoperative and operative findings, usually taken as relative or absolute indications for CBDE, which ones were most frequently encountered. Previously described criteria [18, 19] served to identify and classify as *Papillary Stenosis* those cases where duct stones could not be found upon choledochostomy, yet did show evidence of duct-duodenal drainage difficulties. Such criteria are as follows: *a*) Upper abdominal pain, related to meals, *b*) Intermittent jaundice, *c*) Biochemical evidence, past or present, of cholestasis and *d*) Stasis of contrast material within a dilated duct (over 10 mm), two or more hours post dye injection, as seen on IVC. More than 90 % of the patients, whose ducts required exploration, had evidence, past or present, of clinical jaundice, yet this sign had, either completely cleared or was declining at the time of surgery, except in one patient.

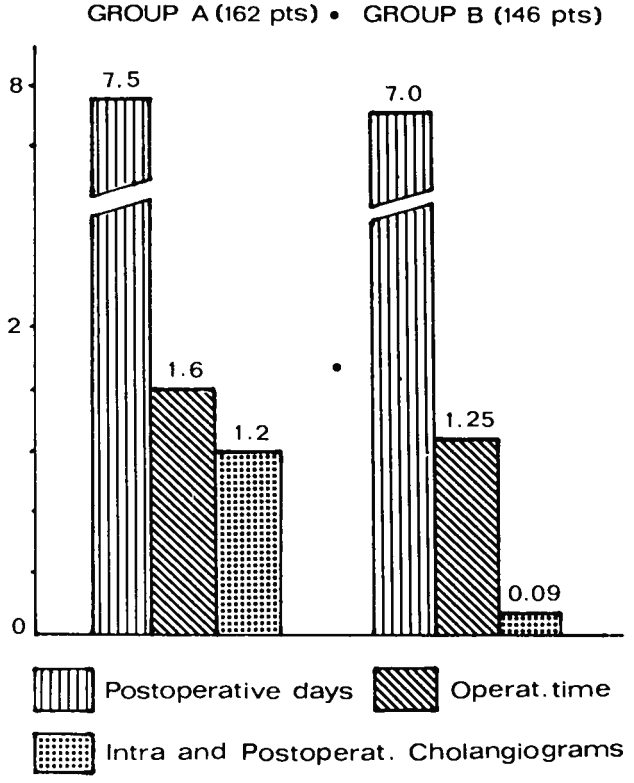

Figure 1: Impact of the parameters evaluated upon the costs, emphasizing the role played by cholangiographic studies (Intra and Postoperative), which were 13 times higher in Group A (1.2 vs 0.09).

In Table 4 we compare the impact and significance of OPC, versus extra-ductal palpation, in detecting unsuspected stones or true anatomical anomalies.

Aschoff's criteria, as quoted by Madden [12, 13] served to classify the duct stones. According to these criteria primary

TABLE 4 **Role played by Preoperative Radiology, OPC and Extraductal Palpation in detecting Intra-ductal Stones and Anatomical Anomalies of the Biliary Tree**

Data	GROUP A n = 162 pts.	GROUP B n = 146 pts.	TOTAL n = 308 pts.
Ducts Explored	44 (27.2 %)	41 (28.0 %)	85 (27.6 %)
Preoperatively proven duct Stones (USG, IVC or ERCP)	24 (14.8 %)	22 (15.0 %)	46 (15.0 %)
Patients with features, other than X-Ray, indicat. need for CDE	19 (11.7 %)	19 (13.0 %)	38 (12.3 %)
Ducts whose need for Exploration was confirmed by Extraductal palpation of Stones	9 (05.5 %)	11 (07.5 %)	20 (06.5 %)
Ducts containing calculi, at the time of Exploration	32 (19.7 %)	29 (19.8 %)	61 (19.8 %)
Anatomical Anomalies detected without OPC **	3 (01.9 %)	3 (02.0 %)	6 (02.0 %)
Anatomical Anomalies detected by OPC §§	1 (00.6 %)	1 (00.7 %)	2 (00.6 %)

** More than 1 cystic duct 2; Cystic duct arising from right hepatic 2; Accessory hepatic, ending up on GB 2.
§§ Papilla located on third duodenal portion 1; Cystic duct terminating next to the papilla, within pancreatic parenchyma 1.

TABLE 5 **Classification of Duct Stones in GROUP A (retrospectively) and GROUP B (prospectively), according to Aschoff's criteria, as quoted by Madden [12, 13]**

Type of Stone	GROUP A-32 Calculi, out of 44 CBDE's	GROUP B-29 Calculi, out of 41 CBDE's	TOTAL-61 Calculi, out of 85 CBDE's
One Single, Primary, Stone	6 (18.8 %)	6 (20.7 %)	12 (19.7 %)
Multiple, Primary, Stones	8 (25.0 %)	6 (20.7 %)	14 (22.9 %)
Secondary Stones, only	5 (15.6 %)	9 (31.0 %)	14 (22.9 %)
Both types present	10 (31.2 %)	8 (27.6 %)	18 (29.5 %)
Unable to classify	3 (09.3 %)	0	3 (04.9 %
Primary Duct Calculi without GB Stones being found	3(9.3 %)	4 (13.8 %)	7 (11.4 %)

calculi are earthy stones, actually formed *de novo* within the duct, susceptible to reform, over and over again, around any nucleating agent, if favorable conditions, such as bile stasis, are met. Any calculus unable to be considered as resulting from stasis is classified as first appearing within the GB and secondarily travelling down through the cystic into the common duct. This type of stone is, once the GB is removed, the only one able to be considered on a later reoperation or endoscopic sphincterotomy to have been missed at primary surgery.

An attempt was made to assess the cost-effectiveness of both approaches under evaluation, ascribing an arbitrary, abstract, value of 1.0 to: *a*) Every 60 minutes of O.R. time, *b*) Every operative and postoperative cholangiogram and *c*) Every postoperative hospital day, as shown in Table 6 and Figures 1 and 2.

In eleven patients of Group A and four of Group B, all having been submitted to simple cholecystectomy, the follow-up is unknown for the past 18-24 months. The follow-up period ranges from two to nine years in Group A and four months to two years in Group B. The long term results were classified as EXCELLENT, GOOD, FAIR and POOR (Table 7), the meaning of which has been, previously, defined.[17, 18]

The technical details of choledochoduodenostomy were as previously outlined [18] and those of sphincteroplasty as advocated by A. Jones.[20] No drains were, ever, left in the GB bed. Likewise, no stents were left within the ducts undergoing a bilio-digestive anastomosis or a sphincteroplasty, except in one of the patients submitted to a Roux-en-y hepaticojejunostomy by the mucosal graft technique.[21] Statistical analysis was undertaken, whenever deemed indicated, by the Student's T test.

IMMEDIATE RESULTS

Two patients died postoperatively, one in each Group, for an overall mortality rate of 0.45 % among patients undergoing simple cholecystectomy ($^1/_{223}$), 1.1 % when choledochostomy was carried out ($^1/_{85}$) and 1.4 % on the sub-group of patients whose ducts were definitively decompressed ($^1/_{71}$), as tabulated in Tables 1 and 2, which outline the morbidity rates, as well.

The percentage of CBDE's (27 %, 28 %) and actual choledocholithiasis cases (19.7 %, 19.8 %) were similar in both groups, irrespective of OPC being utilized or not. In Group A one single case (0.6 %, $^1/_{162}$) of a non palpable, unsuspected, stone was uncovered by OPC, on an apparently normal duct (Table 4). All OPC's of patients, in this Group, undergoing simple cholecystectomy as well as the T-tube, pre-discharge, cholangiograms of 14 ducts submitted to temporary decompression were considered as negative for stones. In two patients of this Group, submitted to definitive drainage of the CBD, a stone, considered irretrievable at the time of surgery was, knowingly, left behind. Both were found free of stones on ERCP control study, one year later, the calculus having, most probably, successfully negotiated the stoma. In Group B none of the type A and C ducts displayed evidence of overlooked stones. One of the type B ducts was found to have a calculus on a cholangiogram, through the cystic duct catheter left in place, one week later. A simple saline infusion was enough to flush it accross the SO, the patient remaining asymptomatic for more than two years, having had two acute pancreatitis episodes prior to surgery. Another patient with a type B duct has had two episodes of cholangitis, one during the immediate postoperative period,

TABLE 6 **Assessment of expenses, ascribing the same given, arbitrary, value to *a*) Every 60 minutes of O. R. time, *b*) Every Cholangiogram and *c*) Every postoperative Hospital day**

		GROUP A (162 pts.)					GROUP B (146 pts.)			
		n = 118	n = 14	n = 30	n = 162		n = 105	n = 41	n = 146	
		a) Cholecyst.	*b*) CBDE, T-tube	*c*) CBDE, Def. Dec.	Total	Avge	*d*) Cholecyst.	*e*) CBDE, Def. D.	Total	Avge
* Operating Time	With OPC	118 × 1,5 = 177	14 × 1,75 = 24.5	30 × 1,75 = 52.5	254	1,6 *	12 × 1.5 = 18	—	—	—
	Without OPC	—	—	—	—	—	93 × 1 = 93	41 × 1.5 = 72	183	1.25
* Cholangiograms	Pre-Explorat.	118 × 1 = 118	14 × 1 = 14	30 × 1 = 30		*	12 × 1 = 12	4 × 1 = 4		
	Post-Explor.	—	14 × 1 = 14	—	190	1.2	—	—	16	0.09
	Pre-Discharge	—	14 × 1 = 14	—			—	—		
* Postoperative Days		118 × 7 = 826	14 × 13 = 182	30 × 7 = 210	1218	7,5 *	105 × 7 = 732	41 × 7 = 287	1019	7.0
** Total		1121	248.5	292.5	1662	10.3 *	855	360	1218	8.3
** Avge per Patient		9.5	17.75	9.75	10.3 *		8.1	8.8	8.3	

without any evidence of choledocholitiasis, as judged from ERCP and IVC studies.

As outlined in Table 3 the findings most consistently associated with patients whose ducts met the criteria for exploration were: *a*) Dilated duct (99 %), *b*) Upper abdominal pain, related to meals (95 %), *c*) Intermittent jaundice (93 %), *d*) Palpable (70 %) and/or actually found (72 %) duct stones and *e*) Biochemical evidence of cholestasis (over 60 %). There were no iatrogenic injuries in the entire series.

Over 64 % of choledochal stones were of the stasis type and no less than 30-40 % had muddly bile with fibrin *debries* within (Tables 3, 4). The approach utilized in Group A was, as an average per patient, 20 % more expensive, yet the clinical efficiency was not any better (Table 6)

The single most significant factors aggravating the costs were the cholangiograms (Figure 1) and the T-tube drainage (Figure 2).

LONG TERM RESULTS

These are as shown in Table 7. A statistically significant higher incidence of POOR results occurred among patients whose ducts, after being explored, underwent a mere T-tube decompression as opposed to those without indications for choledochostomy ($p = 0.001$) as well as to those explored and permanently decompressed ($p = 0.001$). The same significant difference is observed when cases whose follow-up exceeds twelve months are considered (Table 8). The reasons why nine patients, all belonging to Group A, required a reoperation and, therefore, classified as POOR results were as outlined in Table 7. The symptomatology indicating the need for resurgery manifested, in all but one, more than two years after primary surgery. It is worth emphasizing that in only that exceptional case would the cause for recurrent symptoms be discernible by cholangiography at the time of primary surgery (overlooked stones??). Yet, this same patient needed a third operation, three years after the second one (a repeat choledocholithotomy followed by temporary T-tube drainage), for choledochal stones (residual? recurrent?), at which time a side-to-side choledochoduodenostomy was constructed, the patient remaining asymptomatic ever since, three years ago.

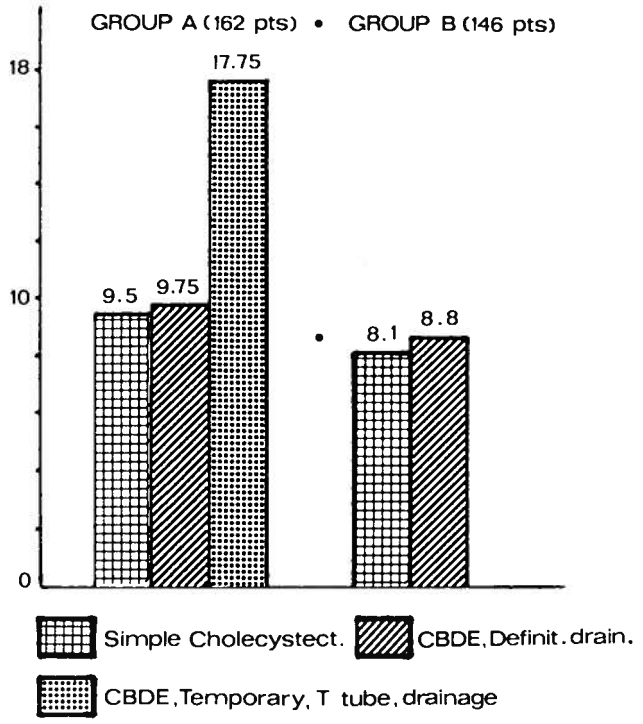

Figure 2: Relative role played by different surgical approaches to the same type of ducts, in what concerns cost-effectiveness.

COMMENTS

The vast majority of surgeons, be it out of firm belief in its value to find unsuspected stones and avoid unnecessary explorations or else because of the ever present threat of a litigious process, utilize OPC on a routine basis. The exact usefulness of this manoeuver, as such, remains unsettled, notwithstanding. In seven large series, using OPC frequently, reviewed by Way,[22] the rate of CBDE's averaged 23.4 % (21 to 27 %), for a positivity rate, among the explored ducts, averaging 58 % (40 to 72 %) and a total positivity rate around 14 % (11 to 17 %), positivity meaning the actual finding of duct stones. As stated by A. A. Gunn[23] 50 to 80 % of patients meet, at least, one of the parameters listed

TABLE 7 **Classification of LONG TERM RESULTS, as defined previously** [17, 18]

	GROUP A (162 patients)			GROUP B (146 patients)	
	a) Simple Cholecystectomy n = 117	*e*) CBDE, T-tube n = 14	*c*) CBDE, Definit. Drain. n = 30	*d*) Simple Cholecystectomy n = 105	*e*) CBDE, Definit. Drain. n = 40
Excellent	73 (61.8 %)	4 (28.5 %)	22 (73.3 %)	69 (65.7 %)	28 (70.0 %)
Good	29 (24.6 %)	4 (28.5 %)	7 (23.3 %)	27 (25.7 %)	11 (26.8 %)
Fair	11 (09.3 %)	1 (07.1 %)	1 (03.3 %)	9 (08.6 %)	1 (02.4 %)
Poor	4 (03.4 %) *	5 (35.7 %) **	0	0	0

* Four patients requiring reoperation for: Stasis Stones 1; Biliary Mud 1; «Papillary Stenosis» 2 (All having had normal OPC's, at primary surgery.

** Five patients requiring reoperation for: «Missed» Stones 1; Stasis Calculi 2; Biliary Mud 1; «Pap. Stenosis» 1 (All having had normal T-tube cholangiograms, at primary surgery) Statistical analysis of the incidence of POOR results:

a) versus *b*) $p = 0.001$; *a*) versus *c*) N. S.; *b*) versus *c*) $p = 0.001$; *d*) versus *e*) No difference; *a*) + *d*) versus *c*) + *e*) N. S.

TABLE 8 **Comparison of the rate of POOR results observed among patients whose follow-up exceeds 12 months**

Operations performed	Nr. of patients requiring further aggressive therapy
a) Simple Cholecystectomy n = 184 (117 of Group A + 67 of Group B)	4 (2.1 %)
b) CBDE, Temporary T-tube decompression n = 14 (all Group A)	5 (35.7 %)
c) CBDE, Definitive Drainage n = 56 (30 Group A + 26 Group B)	0

Statistical Analysis (Student's T test): *b*) versus *a*) p = 0.001; *b*) versus *c*) p = 0.001.

in Table 3, yet only about 20 % (as in our experience) have pathology, once again pathology meaning choledocholithiasis. Our own figures do not differ significantly from the quoted ones, allowing us to believe that our criteria for CBDE are as good or as bad as anyone else's, irrespective of OPC being utilized on a routine or selective basis. In fact, would the assumption of taking an exploration as positive only when stones are found within the duct and only that fact meaning the presence of pathology, the value of routine OPC and of a simple temporary drainage of the explored ducts could hardly be denied. Nevertheless, several facts seem to suggest that choledochal stones should be looked upon as a symptom or a consequence of a deranged function, rather than the pathology itself: *a*) The rate of ducts requiring reoperation was much higher among those meeting the criteria for exploration than among the patients not requiring that step, fact that had been noticed by others, already.[22, 24-27] In present series these rates were 1.7 % ($^4/_{223}$) and 5.8 % ($^5/_{85}$) if the whole series is considered and 2.1 % ($^4/_{185}$) and 7.1 % ($^5/_{70}$), respectively, if we take into account only those whose follow-up exceeds twelve months. It seems reasonable to speculate that the difference would be significantly higher had we used, all along, the widely accepted approach of temporary, T-tube, decompression, still leaving in place the deranged sphincter, rather than definitively draining, either abolishing or bypassing the sphincter, the majority of ducts requiring an exploration. As outlined in Tables 7 and 8 the differences reach statistical meaningfulness only when comparisons are made with the rate of POOR results among the ducts temporarily drained. *b*) The vast majority of ductal calculi were of the stasis type and no less than 30 to 40 % of ducts contained muddy bile (Tables 3, 5). *c*) All ducts containing stones, except two, were dilated over 10 mm.

In one of these, a type B duct of Group B, a simple saline, daily, flush for two weeks was enough to push the stone, without discomfort, into the duodenum, suggesting the presence of a normal sphincter compliance, therefore not leading to duct dilatation. All ducts where stones could not be found (around 30 %), although meeting other criteria for exploration, were dilated, as well. *d*) The preoperative clinical data and operative findings most frequently associated with the ducts meeting the criteria for exploration were the parameters usually taken as defining a vague disease entity, poorly documented physiopathologically, unprecisely designated as *Papillary Stenosis*.[18, 19]. *e*) In only one, out of nine patients requiring reoperation (Table 7), all of them having had normal OPC's and/or T-tube cholangiograms, could we consider the stones, eventually found, as having been missed at primary surgery.

These facts suggest, indeed, that the key problem in any choledochus where stones are retained or else primarily formed or reformed *in loco* is one of duct-duodenum drainage difficulty, secondary to a motility disorder of the SO. This assumption could never be correctly documented by operative cholangiomanometry, since this assessment can not be carried out under conditions approaching the physiological status. However, it has, recently, been shown, by manometric studies utilizing ERCP techniques,[28] therefore under circunstances approximating that status, that there is a motility disorder of the SO in ducts containing stones, as compared to normal controls, showing the presence of retrograde pressure waves pushing bile and/or stones backwards, rather than propelling them into the duodenum.

Though on a mere speculative basis it appears quite reasonable to think of the cases classified as *Papillary Stenosis* (Tables 1, 2), usually considered as negative explorations, as suffering, in fact, from a pathological SO, just not having reached, as yet, the stage of stone formation. In all of them could a dilated duct be documented, as well as a history, past or present, of clinical and/or biochemical cholestasis. It appears that an achalasic type of sphincteric dysfunction, not a stenosis, originates bile stasis setting up the trend for, either, retaining calculi migrated from the GB or primarily forming or reforming stones within the duct itself, around any, otherwise innocent, nucleating agent. This assumption becomes particularly relevant since the presence of lithogenic bile, some time along anyone's daily 24 hours, is a well documented phenomenon, even in healthy men.[29]

CONCLUSIONS

The wisdom of routine OPC seems, therefore, an open to question matter since a morphological type of examination is unable to detect functional disturbances.

Judging from our results, confirming previous findings,[30-32] it seems that extra-ductal palpation can be just as efficient and certainly better cost-effective in detecting stones not yet proven radiologically (Table 4), at least when experienced surgeons are involved. OPC should be selectively utilized on those cases where preoperative data indicate the possibility of intra-ductal stones, yet are found with a normal caliber, non inflamed, duct without palpable calculi (type B duct), or else when facing a severely distorted biliary tree, as a consequence of repeated inflammatory processes. The very low rate of true anatomical anomalies, unable to be picked out by means other than OPC (Table 4), does not seem to justify it on a routine basis, either. Likewise, a mere temporary decompression of a dilated duct, irrespective of the presence or absence of stones, still leaving behind an ill-function SO does not appear as protecting the patient from needing further hospital admissions and aggressive therapy. Besides being a poorly cost-effective and clinically not too efficient measure, the introduction of a tube within an inflamed duct, where supranormal concentrations of pathogenic bacteria are, usually, present, seems to increase or else maintain cholangitis during the immediate postoperative period, enhancing the likelihood of further, long term, stone reformation.[33, 34] A definitive decompression, correctly performed appears as a sound alternative.

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