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CLINICAL BENEFITS AFTER THE IMPLEMENTATION OF A MULTIMODAL PERIOPERATIVE PROTOCOL IN ELDERLY PATIENTS

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ABSTRACT – ***Context*** - Multimodal protocol of perioperative care may enhance recovery after surgery. Based on evidence these new routines of perioperative care changed conventional prescriptions in surgery. ***Objective*** - To evaluate the results of a multimodal protocol (ACERTO protocol) in elderly patients. ***Methods*** - Non-randomized historical cohort study was performed at the surgical ward of a tertiary university hospital. One hundred seventeen patients aged 60 and older were submitted to elective abdominal operations under either conventional (n = 42; conventional group, January 2004-June 2005) or a fast-track perioperative protocol named ACERTO (n = 75; ACERTO group, July 2005-December 2007). Main endpoints were preoperative fasting time, postoperative day of re-feeding, volume of intravenous fluids, length of hospital stay and morbidity. ***Results*** - The implantation of the ACERTO protocol was followed by a decrease in both preoperative fasting (15 [8-20] vs 4 [2-20] hours, $P<0.001$) and postoperative day of re-feeding (1st [1st-10th] vs 0 [0-5th] PO day; $P<0.01$), and intravenous fluids (10.7 [2.5-57.5] vs 2.5 [0.5-82] L, $P<0.001$). The changing of protocols reduced the mean length of hospital stay by 4 days (6[1-43] vs 2[1-97] days; $P = 0.002$) and surgical site infection rate by 85.7% (19%; 8/42 vs 2.7%; 2/75, $P<0.001$; relative risk = 1.20; 95% confidence interval = 1.03-1.39). Per-protocol analysis showed that hospital stay in major operations diminished only in patients who completed the protocol ($P<0.01$). ***Conclusion*** - The implementation of multidisciplinary routines of the ACERTO protocol diminished both hospitalization and surgical site infection in elderly patients submitted to abdominal operations.

HEADINGS - Perioperative care. Postoperative care. Length of stay. Aged. Protocols.

INTRODUCTION

Consistent evidence-based studies have been showing that various routines in perioperative care are useless and in some cases harmful[24]. Most of the current management of surgical patients is grounded in empirism[12]. Overnight preoperative fasting, postoperative re-feeding after ileus resolution, routine use of nasogastric tube and abdominal drains, and preoperative mechanical bowel cleansing for colorectal operations are some of the conventional prescriptions followed by surgeons in many countries[12, 18, 24]. In addition, perioperative nutritional support is frequently neglected[31]. The results reported by both the Enhanced Recovery After Surgery (ERAS) and ACERTO ("Aceleração da Recuperação Total") protocols, in Europe and in Brazil, have shown that the adoption of multimodal strategies of perioperative care are associated with both faster postoperative hospitalization and decrease of infectious morbidity[2, 4, 12, 13, 18, 24].

However, most of the studies reporting the advantages of multimodal protocols have focused on either a specific type of operation such as colorectal resections or in cases of general surgery. We speculate that these multimodal strategies may benefit elderly patients. Life expectancy has been increasing in many countries and it is augmenting the proportion of elderly patients undergoing operations[9, 17]. Elderly patients are most prone to postoperative complications, are usually candidates to major operations, and are most susceptible to homeostasis variations[17]. In addition, they have frequently various co-morbidities such as diabetes, arterial hypertension, chronic pulmonary diseases, and cardiovascular disorders[6, 17].

In 2005, the Department of Surgery of the Julio Muller University Hospital, Universidade Federal do Mato Grosso, Cuiabá, MT, Brazil, initiated the ACERTO project which is a multidisciplinary project with various new routines of perioperative care[2, 4]. The project was named ACERTO because it is a Portuguese word

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meaning "hit the target", "get it right" or "rightness" and at the same time a Portuguese acronym for ERAS.

This study aimed at comparing the clinical outcome before and after the implementation of this multimodal perioperative protocol in a population of elderly subjects who underwent abdominal operations.

METHODS

We prospectively studied all patients above 60 years-old admitted at the Department of Surgery of the Julio Muller University Hospital, and candidate to elective abdominal operations from January 2004 to December 2007. The study design was approved by the Ethical Research Committee of the hospital.

We decided to investigate in the prospective database of the Department of Surgery the clinical outcome of the elderly patients in two distinct periods: before (January 2004 to June 2005), and after the implementation of the ACERTO protocol (July 2005 to December 2007). The new protocol was implemented in July 2005 as previously described[4]. After the commencement of ACERTO protocol, the staff was not obligated to follow the various new routines. Instead, adherence to the new protocol was let be in a free-willing basis. Audits were conducted every 3 months and comparisons between before and after the initiation of the ACERTO protocol were showed to all staff. Figure 1 shows the two protocols followed by the Department of Surgery in the first and second period of the study.

Conventional care	ACERTO project care
Preoperative counseling at surgeon discretion	Oral preoperative counseling
Preoperative fasting of 8 h	Preoperative fasting of 2 h. Six and 2 h before operation the patient drank 400 and 200 mL of a beverage containing 12.5% of maltodextrine
Postoperative feeding after ileus resolution	Early oral or enteral postoperative feeding (6-24 h)
Preoperative nutritional support if malnourished and candidate to major operation	Preoperative nutritional support if malnourished and candidate to major operation
Mechanical bowel preparation for colorectal operations	No mechanical bowel preparation
Intravenous fluids at a rate of 30-50 mL/kg/day usually until the 3-4th PO day	Avoid excessive intravenous fluid (no more than 30 mL/kg/day). No IV fluids for minor operations postoperatively. Discontinuation of IV fluids, if possible, on the 1st PO day
Abdominal drainage and nasogastric tube at surgeon discretion	Avoid drains and nasogastric tubes
Mobilization on the 1st PO day	Early mobilization (if possible on the same day of the operation)

FIGURE 1. Conventional and the ACERTO routines of perioperative care

The surgical procedures were divided as major and minor operations. Major operations included open laparotomies lasting for more than 3 h, and procedures with at least one anastomosis performed at either the gastrointestinal tract or billiary tree. As minor operations were included video or open cholecistectomies, herniorraphies, videolaparoscopies for diagnosis and biopsy, and laparotomies lasting less than 3 h. Nutritional status was assessed by subjective global assessment[11]. Patients were categorized as malnourished or non-malnourished.

Variables collected in both study periods were preoperative fasting time, indication and utilization of preoperative nutritional support, volume of perioperative intravenous fluids, and the day of postoperative re-feeding. The main endpoints were postoperative morbidity, mortality, and postoperative length of hospital stay (LOS). As adherence to ACERTO protocol was not compulsory, the intention to treat analysis was complemented with per-protocol analysis (including patients who completed or did not complete the ACERTO protocol). Chi-square test or Fisher's test were used to compare categorical data. The Kruskall-Wallis test (complemented with Bonferroni test as needed) or Mann-Whitney test was used to compare continuous data. A 5% ($P<0.05$) level was established for significance.

RESULTS

A total of 117 patients (male = 75; 64.1% and female = 42; 35.9%) with a median age of 67 (60-85) year old out of all 514 patients operated on during the period entered the study. Forty-two (35.9%) patients were operated on before (conventional group) and 75 (64.1%) after the implementation of the new ACERTO protocol (ACERTO group). Nineteen (45.2%) patients of the ACERTO group and 35 (45.6%) patients of the conventional group underwent major procedures ($P>0.05$). Table 1 shows the distribution of the operations performed in the two periods. Demographics of patients included in the two periods can be seen in Table 2. In the second period of the study, the ACERTO protocol was fulfilled in 40 patients.

TABLE 1. Distribution of the operations before and after the ACERTO protocol

Operation	Before ACERTO	After ACERTO
Pancreatectomy	2	3
Esophagectomy	1	4
Total gastrectomy	1	2
Subtotal gastrectomy	2	7
Bilio-digestive anastomosis	2	4
Laparotomy	6	6
Colorrectal[a]	11	9
Herniorraphy	8	21
Cholecistectomy[b]	9	19
Total	42	75

[a]Segmental colectomy, abdomino-perineal resection of the rectum, colorectal pull-through, and colostomy closure;
[b]Five operations before ACERTO and 10 after ACERTO were laparoscopic

TABLE 2. Demographics of patients before and after the ACERTO protocol

Variable	Period of the study		*P*
	Before ACERTO (n = 42)	After ACERTO (n = 75)	
Gender (M/F)	27/15	48/27	1.00
Age (years)*	67.5 (60-85)	67 (60-84)	0.29
Operative time (minutes)*	180 (55-540)	140 (30-570)	0.22
Malnutrition (n; %)	23 (54.7)	51 (68)	0.15
Malignancies (n; %)	17 (40.5)	24 (32)	0.36
Major operations (n; %)	19 (42.2)	35 (45.6)	1.00
ASA score (I/II/III)	10/29/3	21/45/9	0.56

*Median and range;
ASA = American Society of Anesthesiologists

Perioperative nutritional support

Malnutrition was found in 74 (63.2%) cases with similar distribution between groups (P = 0.15). All malnourished patients who were candidates for major operations received either oral supplements or specialized nutritional support preoperatively for 7-14 days.

Preoperative fasting

Patients underwent operations by the conventional protocol remained a median of 15 [8-20] h fasting preoperatively, and thus 2-fold longer than the prescribed 8 h. In the second period there was a significant fall (P < 0.001) in preoperative fasting time (4 [2-20] h).

Postoperative feeding

Patients were fed 1 day earlier after the implementation of the ACERTO protocol. Median time for postoperative feeding was the 1st PO day (1st [0-10th] PO day) in conventional group and the same day of operation (0 [0-5th] PO day) in the ACERTO protocol (P<0.001). Reintroduction of diet was earlier in both minor (0 [0-1st] vs 1st [0-2nd] PO day; P<0.001) and major operations (1st [0-5th] vs 2nd [1st-10th] PO day; P<0.001).

Perioperative intravenous fluids

Preoperative intravenous fluids were similarly prescribed in both periods (data not shown). However, the amount of crystalloid intravenous fluids prescribed postoperatively significantly fell after the ACERTO protocol. The median total volume of fluids received per patient was approximately 4-fold greater (P<0.001) before (10.7 [2.5-57.5] L) than after the ACERTO protocol (2.5 [0.5-82] L). This pattern was similar for both minor and major operations. The length of intravenous therapy was longer before the new protocol than after (6 [2-23] vs 3 [1-43] days; P = 0.02). The length of days in intravenous therapy diminished after the ACERTO protocol by 3 days (6[2-23] vs 3 [1-48]; P = 0.02). However, significant difference was only found in minor operations. (Figure 2)

Length of hospital stay

Postoperative stay diminished by 4 days in the second period of the study (6[1-43] versus 2[1-97] days; P = 0.002). In major operations however, there was no significant difference between the two periods (10.5 [3-43] vs 8 [2-97]; P = 0.21) (Table 3). However, in the subset of major operations per-protocol analysis showed that postoperative stay was shortened by 2 days (P<0.01) only in patients who completed the entire protocol (conventional = 10 [3-43] days; non-completed ACERTO protocol = 9 [2-97] days, and completed ACERTO protocol = 8 [2-20] days).

Postoperative mortality and morbidity

Mortality was 3.4% (four cases) with two cases in each period (P = 0.62). Surgical site infection rate significantly fell after the implementation of the ACERTO protocol (19.0%; 8/42 versus 2.7%; 2/75; P<0.001; relative risk (RR) = 1.20; 95% confidence interval (CI) = 1.03-1.39). This difference was due to a significant decrease of surgical site infections after major operations (37.6%; 6/42 vs 5.7%; 2/75; P = 0.01; RR = 1.37; 95% CI = 1.01-1.89). Overall, morbidity rate had a tendency to diminish in the second period of the study (38.1%; 16/42 vs 21.3%; 16/75; P = 0.05; RR = 1.27; 95% CI = 0.97-1.65). There was no difference in the number of anastomotic dehiscence, reoperations, and intra-abdominal abscesses between the two periods (data not showed). Per-protocol analysis showed that surgical infection rate diminished after the new protocol independently of patients who completed or not completed the entire protocol. However, overall morbidity decreased only when the ACERTO protocol was fulfilled (Table 3).

DISCUSSION

The findings showed that the implementation of the ACERTO protocol enhanced the recovery after operations in elderly patients. These benefits were shown in various postoperative parameters. Not only LOS and postoperative stay

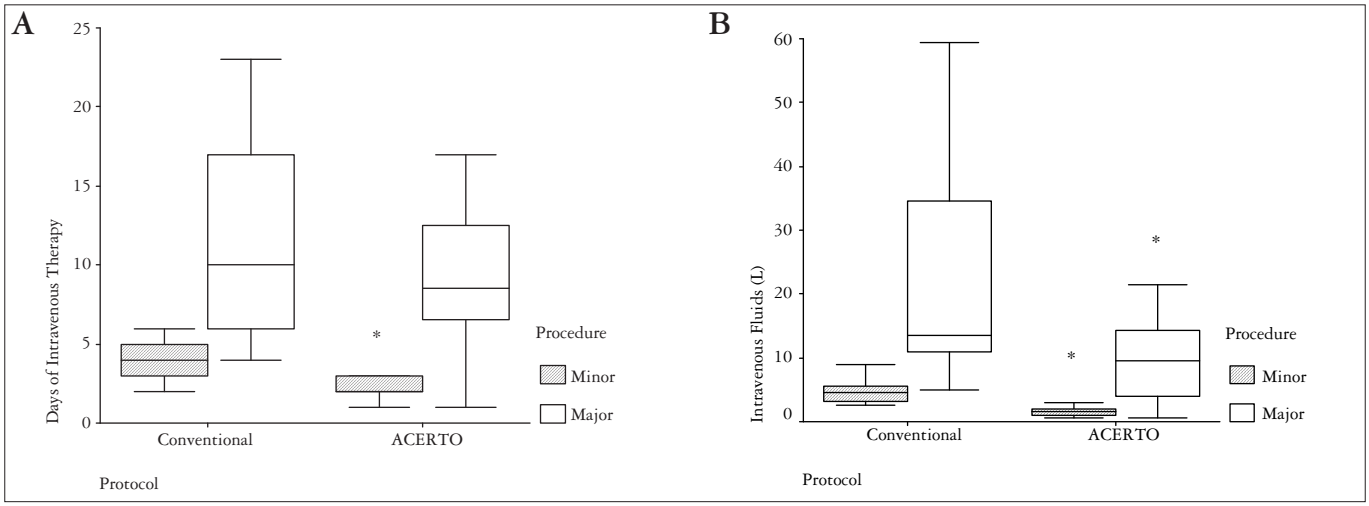

FIGURE 2. Days of postoperative intravenous therapy (A) and total volume of intravenous fluids (B) in the two protocols of the study. *, P<0.01 versus conventional group

TABLE 3. Clinical outcome according to the phase and completion of the ACERTO protocol

Outcome	ACERTO Protocol		
	Before (n = 42)	Complete (n = 40)	Incomplete (n = 35)
Postoperative LOS *	6 (1-43)	2 (1-13)†	7 (1-97)
SSI (n ; %)	8 (19)	1 (2.5)†	1 (2.8)†
Morbidity (n ; %)	16 (38.1)	5 (12.5)†	11 (31.4)
Anastomotic dehiscence (n ; %)	2 (4.7)	2 (5.0)	1 (2.8)
Mortality (n ; %)	2 (4.7)	0 (0)	2 (5.7)

LOS = length of stay; SSI = surgical site infection
*Median and range;
† = $P<0.01$ vs before ACERTO

shortened but also both surgical site infection and morbidity rates diminished. Elderly subjects submitted major operations and completed the entire ACERTO protocol were the most benefited. These results are significant because surgical site infection in elderly patients is associated with approximately four times greater mortality[17]. Moreover the findings indirectly suggest that an important institutional endpoint as hospital costs was probably cut down.

Perioperative multimodal approaches have significantly impacted the outcome in general surgery[13, 18]. Various traditional surgical routines such as routine use of nasogastric intubation and abdominal drains when examined by the sight of the evidence based medicine paradigm have failed to demonstrate their usefulness[12, 22, 25]. In opposition to traditional 6-8 hours of "nil by mouth" routine, the abbreviation of pre-operative fasting not only is safe but also decreases insulin resistance[20, 23] and preserves skeletal muscle mass after surgery[32]. In addition the prescribed fasting time is usually enlarged by several reasons[2, 4]. The findings in the present study showed that it may increase by 2-fold. This delay may initiate a metabolic response to fasting that may enhance the catabolic response after the trauma. The implementation of the new protocol safely reduced preoperative fasting time by 3-fold. Intake of carbohydrate beverage 2 hours before operation may diminish postoperative discomfort[17] and episodes of nausea/vomiting[3, 15]. Aged subjects are most fragile and thus more susceptible to complications due to variations of the homeostasis[17].

Various randomized trails[1, 29] and meta-analisys[5, 19] concluded that early feeding after intestinal anastomosis is safe, reduces postoperative ileus, shortens LOS, and does not impair the healing of gastrointestinal anastomosis[19]. Our findings showed that aged subjects were safely fed 1 day earlier than before contributing to both rapid freeing of intravenous fluids and early hospital discharge.

Malnutrition is very prevalent among aged people and a continuing source of concern, particularly among hospitalized patients[27]. Our data are in accordance and have showed that malnutrition is highly prevalent in this subset of surgical patients. There were no modifications on perioperative nutritional support data before and after the new protocol. This finding was due to our previous concept in the former protocol that remained in the ACERTO protocol: undernourished patients should receive pre-operative nutritional support for 7-10 days[2, 4].

There are serious clinical implications of excessive perioperative fluid administration. In addition, a worst tolerance to intravenous fluids in either malnourished or elderly patients is well accepted[16]. Regimens of restrict use of fluids are associated with less postoperative complications and shorten postoperative stay[7]. Generous intravenous fluids therapy increases body weight and may cause edema, pulmonary complications, and prolonged ileus[7, 16, 21, 30]. A significant fall of intravenous fluid prescription at postoperative period was achieved after the ACERTO protocol was initiated. In addition, the number of days of intravenous therapy was reduced by 3 days. The new protocol reduced by 4-folds the total volume of fluids which represented a median reduction of approximately 8 L of fluids per patient. This modification has certainly implied in the overall postoperative results.

The ACERTO protocol abolished in our hospital the use of preoperative mechanical preparation of the colon for elective colorectal operations. This police was based on various meta-analysis that have consistently documented that there is no benefit in cleansing the large bowel preoperatively and furthermore, this traditional preoperative care may be harmful and increase the risk of colonic anastomotic dehiscence[8, 28]. A recent well-design multicentric randomized trail including 1400 patients conclude that mechanical bowel preparation before elective colorectal surgery can safely be abandoned[10]. Accordingly, the number of anastomotic dehiscence in this study was not increased after the adoption of the new protocol.

The difficulties of implementing a multimodal strategies like the ACERTO protocol were expected since the adherence to the new routines was let be in free-willing basis. Therefore only 53.3% of cases completed the entire protocol. These difficulties have been reported in a recent paper[26]. Possibly, a much longer period of experience is necessary to rupture with the longstanding traditions in conventional care. Nonetheless elderly subjects who completed the protocol have a significant improvement in the outcome.

The study has some limitations that need to be pointed out. The two groups were not randomized, they were unequal in size and conclusions were based upon comparisons between two periods. However the two groups were similar in many clinical characteristics such as the incidence of malnutrition, major procedures, malignancies, ASA score, and length of operative time. Thus, the best results may reflect the evolution of perioperative care between the two periods.

Our findings are in complete agreement with other authors and guidelines that advocate the changing of the traditional routines of perioperative care[13, 24, 32]. The overall results allow us to conclude that the adoption of the ACERTO protocol in elderly patients was followed by a significant fall of surgical site infection rate and faster recovery of the patients.

CONCLUSIONS

The implementation of multimodal strategies may provide clear benefits for aged patients submitted to abdominal operations, mainly on the digestive tract.

Aguilar-Nascimento JE, Salomão AB, Caporossi C, Diniz BN. Benefícios clínicos após a implementação de um protocolo multimodal perioperatório em paciente idosos. Arq Gastroenterol. 2010;47(3);178-83.

RESUMO – ***Contexto*** - Protocolos multimodais de cuidados perioperatórios podem acelerar a recuperação pós-operatória. Fundamentadas na medicina baseada em evidência, essas novas rotinas mudam as prescrições convencionais em cirurgia. ***Objetivo*** - Avaliar os resultados de um protocolo multimodal (protocolo ACERTO) em pacientes idosos. ***Métodos*** - Estudo de coorte histórica não aleatório realizado na enfermaria de cirurgia de um hospital universitário terciário. Cento e dezessete pacientes com idade igual ou superior a 60 anos foram submetidos a operações abdominais eletivas sob um protocolo convencional (n = 42; grupo convencional, janeiro 2004-junho 2005) ou um protocolo multimodal denominado ACERTO (n = 75; grupo ACERTO, julho 2005-dezembro 2007). As principais variáveis de resultado foram: tempo de jejum pré-operatório, tempo de realimentação pós-operatória, volume de fluidos intravenosos, tempo de internação e morbidade. ***Resultados*** - A implantação do protocolo ACERTO foi acompanhada de queda do tempo de jejum pré-operatório (15 [8-20] vs 4 [2-20] horas, *P*<0.001), do dia de realimentação pós-operatória (1º [1º-10º] vs 0 [0-5º] dia de pós-operatório; *P*<0,01) e do volume de fluídos intravenosos (10,7 [2,5-57,5] vs 2,5 [0,5-82] L, *P*<0,001). A mudança de protocolo reduziu o tempo médio de internação hospitalar em quatro dias (6[1-43] vs 2[1-97] dias; *P* = 0,002) e a taxa de infecção do sítio cirúrgico em 85,7% (19%; 8/42 vs 2,7%; 2/75, *P*<0,001; risco relativo = 1,20; 95% intervalo de confiança = 1,03-1,39). Análise per-protocolo mostrou que a permanência hospitalar em operações de grande porte diminuiu apenas no subgrupo de pacientes nos quais o protocolo foi completo (*P*<0,01). ***Conclusão*** - A implantação de rotinas multidisciplinares do protocolo ACERTO diminuiu a hospitalização e a infecção de sitio cirúrgico em pacientes idosos submetidos a operações abdominais.

Descritores – Assistência perioperatória. Cuidados pós-operatórios. Tempo de internação. Idoso. Protocolos.

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