TO RETURN OR TO DISCARD?. RANDOMISED TRIAL ON GASTRIC RESIDUAL VOLUME MANAGEMENT

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KEYWORDS

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SUMMARY

Background: The control of gastric residual volume (GRV) is a common nursing intervention in intensive care; however the literature shows a wide variation in clinical practice regarding the management of GRV, potentially affecting patients' clinical outcomes.

The aim of this study is to determine the effect of returning or discarding GRV, on gastric emptying delays and feeding, electrolyte, and comfort outcomes in critically ill patients.

Method: A randomised, prospective, clinical trial design was used to study 125 critically ill patients, assigned to the return or the discard group. Main outcome measure was delayed gastric emptying. Feeding outcomes were determined measuring intolerance indicators, feeding delays and feeding potential complications. Fluid and electrolyte measures included serum potassium, glycaemia control and fluid balance. Discomfort was identified by significant changes in vital signs.

Results: Patients in both groups presented similar mean GRV with no significant differences found (p=0,111), but participants in the intervention arm showed a lower incidence and severity of delayed gastric emptying episodes (p=0,001). No significant differences were found for the rest of outcome measurements, except for hyperglycaemia.

Conclusions: The results of this study support the recommendation to reintroduce gastric content aspirated to improve GRV management without increasing the risk for potential complications.

INTRODUCTION

In healthy adults, the gastrointestinal (GI) tract produces seven to nine litres of secretions daily. Of these secretions, "*most are absorbed in the small bowel and about 500 to 600 ml reaches the colon, where another 350 ml is absorbed; 150 g of stool remains"* (Jeejeebhoy, 2002; Jeejeebhoy, 1977).

The rate of gastric emptying is regulated by neural and humoral mechanisms and in fasting conditions, retention of 10 to 100 ml of fluid gastric content can be considered physiological (Edwards, 2000; McClave, 1992).

Delayed gastric emptying is common in critically ill patients, occurring in approximately 50% of mechanically ventilated individuals. This may be due to impaired gastroduodenal motility related to patients' clinical severity, premorbid conditions, and pharmacological and surgical treatments. Prevention and management of delayed gastric emptying include the insertion of a nasogastric tube (NGT) to aspirate gastric contents. (Deane et al., 2007; Dive et al., 1994; Ritz et al., 2001, Stechmiller et al., 1997).

Enteral feeding (EF) is considered the preferred method of nutritional support for the critically ill. EF offers nutritional advantages, contributes to bowel flora maintenance, reduces infection risks, and avoids the potential adverse outcomes of parenteral nutrition. However, it is not exempt from complications (pulmonary aspiration, tube occlusions or intolerance). In this population, GI dysmotility implies feeding via a NGT is often associated with large gastric residual volumes, which may lead to increase the potential for regurgitation and vomiting (McClave et al., 1992; Edwards & Metheny, 2000; Williams and Leslie, 2004) and a delay in the achievement of nutritional goals, because of under-

delivery of feeds (Engel, 2003; Marshall and West, 2006; McClave, 1999; Pingleton, 2001).

A common nursing intervention to assess gastrointestinal function and to minimise potential complications from enteral nutritional therapy (ENT) in critically ill patients, is the regular checking of gastric residual volume (GRV) by aspiration with a syringe. But like in many other clinical procedures, standards for the management of GRV are not evidence-based. Reports in the literature show a wide variation in nursing practices, regarding the frequency of GRV checks, whether to instil gastric contents obtained to the patient or to discard volume aspirated, and what should be considered maximum GRV (Goodwin, 1996; Metheny, 1993; Mori et al., 2003; Pullen 2004; Valls et al., 2006; Williams and Leslie, 2004). Thus, based on empirical observations and clinical experience, authors have proposed maximum GRV for critically ill patients between 50 and 500 ml (Marshall and West, 2006; McClave, 2002; Metheny, 2004; Murphy 1999).

A different approach to GRV management is emerging. High gastric residual volumes is not always indicative of gastric stasis (Burt and Lentz, 2001; Jostee et al., 1999; McClave and Snider, 2002, Williams and Leslie, 2004), a low GRV does not protect against aspiration pneumonia (Lukan et al., 2002; McClave and Snider, 2002; Pinilla et al., 2001; Powell et al., 1993, Williams and Leslie, 2004) and as stated by Zaloga (2005), "*the level at which GRV predicts aspiration risk still remains unknown*". While the scientific community is trying to respond the utility of the bedside measurement of GRV (Chang et al., 2007; Zaloga, 2005), some nurses discard gastric contents while others reintroduce it

to the patient, partially or completely, depending on their assessment (Booker et al., 2000; Marshall and West, 2006; Mateo, 1996). Individual beliefs, unit tradition, expert opinion or nurse's experience guide the decision. Some authors support instilling gastric content aspirated in order to contribute to the maintenance of gastric juices and the electrolyte balance. Others hypothesise discarding as the best option in order to avoid tube contamination, infection risks, tube complications like occlusion, as well as to prevent volume retention secondary to delayed gastric emptying (Booker et al., 2000).

Objectives

Authors in this inquiry looked for responding the clinical question: *what is better for the patient, to return or to discard the GRV aspirated*?.

The main purpose of this study was to investigate, in adult critically ill patients, the effects of returning versus discarding gastric residual volume on gastric volume and gastric emptying delays.

Specific goals included to evaluate whether the gastric residual volume determination with the GRV reintroduction technique augments the incidence of: (1) NGT obstructive complication episodes; (2) pulmonary aspiration episodes; (3) intolerance episodes (nausea, vomiting, diarrhoea and abdominal distension); (4) enteral feeding delays; (5) hyperkalaemia episodes; (6) hyperglycaemia episodes and (7) discomfort episodes, when compared to the discarding group.

METHOD

Study design

This prospective, randomised, non-blinded, clinical trial was conducted over one year period, in a single medical-surgical intensive care unit (ICU) of a public university hospital. Institutional ethics committee approval was granted and informed consent was obtained from the patient or a relative legally authorised.

Participants

Any patient admitted to the ICU, aged 18 or more, haemodynamically monitored, enterally or parenterally fed, all of them needing GRV controls due to their condition and treatment, with a length of stay estimated at greater than 48 hours, was considered eligible to enter the study.

Exclusion criteria included patients connected to an intermittent gastric aspiration system because of paralytic ileum, bowel obstruction, gastric fistula or gastric surgery.

A computer-generated random list and sealed envelope were used to randomise patients to the GRV return group or the GRV discard arm.

It was calculated that using an alpha of 0.05, 59 patients would need to be entered in each group to have an 80% power of detecting a difference greater than of 10% in the rate of delayed gastric emptying episodes.

Data Collection

Each subject remained in the study until any of the following end points was met: no need for further GRV controls (medical indication of NGT withdrawal), critical adverse event associated to the procedure (pulmonary aspiration or

cardio respiratory arrest during or immediately after the procedure), transferring out of ICU, faecal aspirates, major protocol error, or death.

All data were obtained by the primary investigators or by the trained registered nurses from the ICU.

Gastric residual volumes were checked, as usual in the unit, every six hours, aspirating the content through a 60 ml syringe. Stomach was considered aspirated to dryness when no more gastric content could be obtained with the aspiration syringe. No position changes were performed during the GRV controls. Research team and the medical staff determined that GRV would be instilled to patients in the return group, up to a maximum of 250 ml per check. If volume obtained from aspiration was greater than 250 ml, surplus from that cutting point was discarded. Exact measurement of the amount aspirated and returned was recorded in the patients' data collection forms.

Gastric emptying delay (GED) was defined as the difficulty in maintaining gastric residual volume within safe limits (GRV below 5 ml/kg) (Horn et al. 2004). Based on the available evidence, it was categorised as light GED (151 - 250 ml / 6h), moderate GED (251 – 350 ml / 6h) or severe GED (> 350 ml / 6h). All patients in the study had head-of-bed kept at 30º or greater.

Feeding rhythm (delays) in patients with ENT was controlled through the determination of the difference (>20%) between the amount prescribed and the amount administered every 24h. Administration of the formula was continuous and controlled by a pump delivery system. ENT was temporally withheld if any of the following conditions were present: GRV greater than 500 ml (Figure 1);

vomiting; need of radiological or surgical procedures and diarrhoea for more than 48 hours.

Nasogastric tube was checked for occlusion every shift. Prescribed formulas administered and standards for NGT care and maintenance, followed by all nursing staff, are detailed in Figure 2.

Daily scheduled lab test (7 a.m.) was obtained for serum potassium, sodium, glycaemia and proteins. Hypokalaemia was defined as a blood potassium value < 3.5 mmol/L in the 7 a.m. lab test. Hyperglycaemia as blood glucose value > 8 mmol/L and hypoalbuminemia considered when albumin was < 0.54 mmol/L. Fluid balance was calculated partially, every shift and at 8 a.m. on a 24-hour basis.

Before and after each GRV check, vital signs and Ramsey Sedation Scale (Ramsay MA et al., 1974) were assessed to identify any signs of discomfort in the patient due to the procedure.

Patients were prospectively monitored for nausea, vomiting, abdominal distension (checking abdominal circumference following standardised procedure every 24 hours), diarrhoea (three or more soft blob-like, mushy or liquid stools / 24 hours) (Booker et al., 2000; Lewis and Heaton KW, 1997) and pulmonary aspiration. For patients with artificial airway, the standard blood glucose monitors to check pulmonary aspirates were prepared to use.

Investigators also gather data on patients' medication, especially prokinetics and drugs affecting gastric emptying along with other general data of interest.

Data analysis

Sample characteristics and main outcomes were analysed by using frequencies, measures of central tendency, Wilcoxon test, chi square or pair sample *t* test as appropriate. Univariate analysis of variance (ANOVA) was use to analyse the factors contributing to residual volume.

To assess the adequacy of randomisation, groups were compared by the chi-square test when appropriate, Fisher's exact test for categorical variables, and Wilcoxon or Kruskal-Wallis tests for continuous variables.

Significance was established at an alpha value of 0.05. Descriptive statistics were used to report complications.

All analysis was made using *R* release 2.3.1 (R Development Core team, 2006).

RESULTS

We finally recruited 125 consecutive patients; 63 were randomly assigned to the intervention (return) group and 62 to the control (discard) group. Two patients in the intervention arm and one assigned to the control group could not be included in the final analysis because of a shorter than expected length of stay and a major protocol error (has GRV returned) (Figure 3). Overall, 61 patients had their GRV discarded and 61 returned.

The baseline features of the patients in each group were similar and no significant differences were found with regard to age, sex, primary and secondary diagnosis, APACHE II and NEMS scores, mechanical ventilation and enteral feeding (Table 1).

Patients in the intervention group showed a slightly lower total mean GRV although this difference has no statistical significance ($p < 0.111$) (Table 2). This result was consistent through time comparisons and when adjusting through ANOVA model to confusion variables: hyperglycaemia, prokinetics and medication delaying gastric emptying, including opiates, atropine, barbiturates and neuromuscular blocking agents ($F = 0.847$) (Pr (>F) 0.359). Mean ratio of gastric content reintroduction in the intervention group was 0.93 (SD 0.25). GRV was not related to diagnosis, demographic variables or to APACHE II score.

Incidence and severity of delayed gastric emptying (GED) episodes were lower in the intervention group ($p = 0.001$). The number of light and moderate GED episodes was double in the discard group (Table 2). Severe GED episodes were observed both in patients feed enterally and those with parenteral nutrition and were also more frequent in the control group.

No differences were found between groups in the number of patients with ENT and the mean prescribed volume or the administered EF volume. The type of feeding formula and NGT (Salem tube_16 G) were comparable for the two study groups. NGT remained in place while the patients were in the study, for similar mean duration. Episodes of tube blockage and accidental extubation did not occur. Neither statistically significant difference in the number of ENT days was detected, although the mean was slightly greater in the control group. Incidence of a difference greater than 20% between the amount of ENT prescribed and the volume administered was similar in both groups ($p = 0.91$) (Table 3).

Fluid balance and serum electrolyte outcomes were comparable in both groups with no statistically significant differences, except for hyperglycaemic episodes, which were more frequent in the intervention group ($p = 0.001$). Episodes of hyperglycaemia correlate with a higher frequency of moderate and severe GED despite of the group ($p = 0.001$). More patients presented hypokalaemia at any moment of the study in the control group, although this difference was not statistically significant ($p = 0.611$). The number of hypokalaemic episodes distributed similarly in the two groups (Table 4).

For any of the statistical tests applied, no differences were identified between the study groups in relation to the discomfort outcomes. Mean pulse, blood pressure and Ramsey measurements resulted homogeneous with a slightly increase of BP in the intervention group. Neither difference was observed in the comparison of the vital signs measurements before and after the intervention.

No significant differences were found for the other outcome measures and the overall rate of complications was similar in both groups (Table 5). Complication rates were null for nausea and pulmonary aspiration and insignificant for vomiting. Four percent of patients more in the intervention group presented diarrhoea at any time of the study, although this value has no statistical significance ($p = 0.709$). Mean days with diarrhoea was similar in both groups. Mean GRV was lower in patients with diarrhoea despite the group, when compared to patients who did not present diarrhoea ($p = 0.003$). All patients presenting diarrhoea were fed with enteral nutrition.

Abdominal distension was documented in more patients from the control group, with no statistical difference observed ($p = 0.071$).

DISCUSSION

In the light of these results, reintroducing the gastric content aspirated, up to 250 ml per check, does not increase the number or the severity of complications. Half the patients in the intervention group presented light or moderate GED and less participants suffered from severe GED when compared to the control. This could suggest that reintroducing the GRV aspirated does not increase the total GRV and could have an effect in maintaining GRV at closer physiological levels. This result correlates with the recommendation of returning gastric aspirate to patients (Lin and Van Citters, 1997; McClave et al., 2002; Williams and Leslie, 2005). As stated by Jooste et al. (1999), "*having high residual gastric volumes does not always imply gastric stasis"*. When GRV is higher than 250 ml clinicians should be alerted to potential complications and should activate careful bedside monitoring to manage fluid, nutritional and electrolyte outcomes. ENT delivered via nasojejunal tube has also shown promising results and may be other forms to improve GRV management (Davies et al., 2002).

Our results coincide with Van Der Voort's (2001) in detecting no relationship between GRV and APACHE II score.

The absence of tube blockages in any group does not correlate with the results of Booker et al. (2000). The recommendation of regularly flushing the NGT with water (Williams and Leslie, 2005) was followed by nurses in the unit. This fact may have contributed to prevent this complication. In contrast, our results do

correlate with Booker's (2000) in relation to an equal distribution of feeding delays between both groups.

Patients were kept at safety position (head-of-bed at 30º elevation) and continuous ENT delivery via peristaltic pump assured constant delivery of small volumes in the stomach (Stevens et al., 2002). These factors have probably contributed to reduce aspiration risk.

Some authors (De Boer et al., 1992; Mallampalli et al., 2000; Zhao et al., 2006) described the important role of hyperglycaemia in oesophageal motility, decreasing inferior oesophageal sphincter pressure, the speed of the oesophageal peristalsis, and in the delay of gastric emptying. In this sense, a trend has been found on detecting a higher number of hyperglycaemic episodes in patients in the intervention group and a relation between moderate and severe GED and hyperglycaemia despite the group.

Discarding gastric aspirate may result in loss of gastric fluids and electrolytes (Cataldi-Betcher et al., 1983), but this hypothesis cannot be verified with our work as we could not identify any differences.

It has been stated that "*the uncertainty existing with regard to the measurement, interpretation and management of GRV influences nursing practice"* (Williams and Leslie, 2005). This randomised control trial could contribute to diminish this uncertainty but it is not exempt from some significant limitations. Due to the features of the intervention, blinding was not feasible. Although the sample size was appropriate for the research question, larger sample sizes would procure a higher level of evidence and a multi-centre approach could be more appropriate.

The authors have not investigated the role of ICU nurses' expertise on the prevention and management of potential complications. Care standards were properly applied in the unit; however, the data collection period excluded 2 months in summer, when nursing turnover is higher and probably, less skilled registered nurses are working. This could introduce potential bias in the results. The authors agree with Booker et al. (2000) in that the low incidence of serious complications could be related to proficient nursing care provided, but it should be empirically proved.

Limiting the reintroduction of GRV up to a maximum of 250 ml per check can be considered another important limitation. Results are based on instilling this amount to patients; and the probable outcomes if the total GRV would be returned, can only be inferred, although the mean percentage of volume reintroduction was greater than 90%.

In this study, all patients regardless the group, received 40mg of *Omeprazole* per 24h, but this was a standard for any patient admitted in the ICU. Additional administrations or other acid inhibiting agents administration were not controlled. These drugs are described to inhibit the gastric secretion with the corresponding decrease of the GRV (Chang et al., 2007).

Difficulties have also been found in identifying an instrument to measure discomfort in critically ill patients. In the absence of a validated tool, the literature suggested authors to use Ramsey sedation scale and blood pressure as these parameters are usually controlled in this population as indicators of the need for analgesia, sedation and the severity of pain and discomfort. The

necessary continuous haemodynamical management of critical patients could have masked the results.

Finally, some authors have stated that reintroducing GRV aspirated could precipitate infections due to manipulation (Booker et al., 2000; Pingleton et al., 1986; Williams and Leslie, 2005). In this study we have not been able to gather data on microbiological results; but ICU physicians considered that diarrhoea was not attributable in any of the patients to infection or contamination of the gastric tube. Diarrhoea was not controlled for antibiotic intolerance and this could also be considered a significant limitation of the study.

CONCLUSIONS

In conclusion, while better evidence is going to be produced by the scientific community, the results of this study support the recommendation to reintroduce gastric aspirate (up to 250 ml per check) in critically ill patients to procure a more physiological gastric content management approach without increasing the risk of severe potential complications, while controlling for glycaemia.

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