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A Retrospective Population Based Observational Cohort Study to Assess the Effect of High Osmolality and Low Osmolality Water Soluble Oral Contrasts in Adhesive Small Bowel Obstruction

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1. Abstract

1.1. Objective: To review and assess the effectiveness of high and low osmolality water-soluble contrast agents in the resolution of adhesional small bowel obstruction (aSBO).

1.2. Summary & Background Data: SBO continues to be a major cause for surgical admission amounting to up to 17% of admissions in the evaluation of acute abdominal pain. Most cases of SBO can be successfully treated conservatively with nasogastric tube decompression and subsequent administration of water-soluble contrast.

High osmolality compounds are frequently used but are known to cause significant acute pulmonary oedema, chemical pneumonitis, respiratory collapse, and death. There is a paucity in research on low osmolality contrast agents that have a better safety profile.

1.3. Methods: The exposure in this study was successful water-soluble contrast challenge. Primary analysis compared those who achieved successful water-soluble contrast challenge compared to the individuals who still required surgical intervention. Secondary analysis observed the number of patients who were readmitted within 6 weeks with SBO despite resolution of SBO with a successful water-soluble contrast challenge.

1.4. Results: In 235 patients, there was no statistically significant difference in successful challenge or need for surgery. Additionally, there is no statistical difference in readmission rate or hospital inpatient stay.

1.5. Conclusion: High and low water-soluble contrast agents are equally useful as an adjunct in management of aSBO, and furthermore, the difference in osmolality has no statistically significant effect on rates of successful water-soluble contrast challenge, readmission rate or hospital inpatient stay. Low osmolality agents have a superior safety profile without sacrificing efficacy.

2. Introduction & Background

Small bowel obstruction (SBO) continues to be a major cause for surgical admission amounting to up to 17% of admissions in the evaluation of acute abdominal pain in Australia [1]. The vast majority of SBO is secondary to post-operative adhesions which is thought to occur after any abdominal surgery [2,3]. Most cases of SBO can be successfully treated with non-operative or conservative measures including making patients nil by mouth, intravenous fluid rehydration and nasogastric tube (NGT) decompression [4,5]. However, in approximately 20% of cases, emergent surgical intervention is indicated if there are any signs of strangulation, ischaemia, or perforation [5]. The mortality from SBO ranges from 5-8% [6] rising up to 25% if bowel ischaemia is present and there are delays in surgical intervention [6]. The administration of water-soluble contrast is one of the most commonly used conservative methods in resolving SBO. Whilst the majority of patients respond adequately within 48 hours post admission [7] there is no consensus when conservative management should be considered unsuccessful or which patients are likely to respond [7]. Many studies have evaluated the role of water-soluble contrast and its

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role in the resolution of SBO. The studies aimed to predict water-soluble contrasts' ability in resolving SBO independently or distinguishing SBO that would ultimately require surgical intervention [5-9]. Water-soluble contrast transit time to the rectum has been shown to be a reliable indicator of successful conservative management [9,10] whilst other studies have indicated that failure of the above necessitates prompt surgical management [11]. Other authors have suggested that the use of water-soluble contrast has resulted in resolution of symptoms, shortened inpatient stay and reduced healthcare burden both in costs and resources [8,11,12]. Several studies have evaluated the therapeutic value of water-soluble contrast in SBO with the extant literature supporting its use as a predictive test for non-operative resolution of adhesive small bowel obstruction, reducing the need for surgery and shortened hospital inpatient stay [5-9]. However, systematic reviews have concluded that further research needs to be conducted to comment on mortality benefits or incidence of complications [5-9].

Gastrografin, a hyperosmolar solution, is the most common water-soluble contrast medium utilised, consisting of a mixture of sodium diatrizoate and meglumine diatrizoate. The osmolality of Gastrografin and its analogues is 2150 mOsm/L which amounts to 7.5x normal plasma osmolality (at 285 mOsm/L). The proposed mechanism involves the creation of a pressure gradient that shifts fluid intraluminally decreasing bowel oedema and enhancing bowel motility secondary to effects on visceral smooth muscle contractility [3,5]. The extant literature actively compares standard conservative management with the additional administration of oral water-soluble contrast, however, excludes or does not compare the use of other types of water-soluble contrast. Although oral water-soluble contrast is generally accepted as a safe intervention, the major drawback of hyperosmolar fluid is inadvertent aspiration [13]. Due to its ingredients and nascent mechanism of action, it can cause significant acute pulmonary oedema, chemical pneumonia, respiratory collapse, and death [13]. Despite this, there are few studies that evaluate low osmolality water-soluble contrast mediums such as Iohexol -marketed under the name Omnipaque -which depending on the concentration can range between 1.1 - 3times the osmolality of plasma -up to 844 mOsm/L. According to the FDA, and an observational case-control trial by Hwang, pulmonary oedema from Omnipaque is rare and has been labelled useful alternative in patients with suspected bowel perforation or those where aspiration of contrast medium is a possibility [13,14]. In routine follow-through examinations Omnipaque is better tolerated and has better contrast medium density and diagnostic visualisation in small bowel [15]. In 1998, authors suggested that there was no difference between Gastrografin and Omnipaque with respect to symptom resolution as well as transit time between ingestion and its radiological presence in the caecum [16]. Researchers in Milwaukee positively report that the use of low-osmolar water-soluble contrast confer to reduced length of inpatient stay and

need for operative management [14]. Furthermore, a study in Boston introduced a low osmolar water-soluble contrast medium to their SBO pathway saw reduced hospital length of inpatient stay, however, rates of readmission, surgery and need for bowel resection for those undergoing surgery were unchanged [17]. Additionally, lack of clarity on the timing of the intervention and lack of pre-interventional standardisation of the SBO pathway confounded conclusions [17-20].

2.1. Aims

The primary outcome in this study was the incidence of a successful water-soluble contrast challenge. Our secondary outcome measures evaluated the need for surgical intervention or readmission despite resolution of SBO with a successful water-soluble contrast challenge.

3. Methods

3.1. Setting

Mackay Base Hospital is a regional hospital in Queensland Australia that serves a population of approximately 180,000, we typically admit over 100 cases of SBO annually with increasing incidence as life expectancy and population increases. Rockhampton Hospital is a similar regional hospital in Queensland Australia which serves a population of around 250,000 patients. These two sites were selected as they had similar patient baseline demographics such as age, gender spread, BMI, prevalence of diabetes mellitus and number of previous operations as well as medical factors such as surgical staffing, expertise and ICU capacity. The non-operative SBO pathway of both hospitals are similar. After establishing nil by mouth and intravenous fluid resuscitation, the stomach and small bowel is decompressed with an NGT, following this, 100ml of water-soluble contrast is administered via the NGT which is subsequently spigoted. After this plain film radiography was used to identify passage of contrast into the colon signifying resolution of obstruction. There is a slight variation in the timing of plain film radiography between hospital sites with Mackay performing plain film radiography at 6 hours and 24 hours post water-soluble contrast administration. At Rockhampton Hospital, plain film radiography is undertaken at 30min, then at 4, 6, 12 and 24 hours post water-soluble contrast administration, stopping when the contrast has reached the colon. For both sites, a successful water-soluble contrast challenge is defined as the contrast reaching the colon within 24 hours. The main difference is the use of the water-soluble contrast. Mackay Base Hospital uses the high osmolar agent Gastrografin, whilst Rockhampton uses the low osmolar agent Omnipaque. This presents an opportunity to compare the two different oral contrast agents and review if there is any significant difference in outcomes and if Omnipaque could pose as a safe alternative to Gastrografin.

3.2. Design

This retrospective population based observational cohort study in-

cluded patients who were admitted to both hospitals for SBO. This study relied on population-level administrative data collected via hospital record (iEMR) sequestration by investigators for all cases coded with intestinal obstruction between January 1st 2020 to January 2021. All consecutive patients were considered for the study period. Inclusion criteria considered all cases of adhesional SBO that was treated with water-soluble contrast. Patients who received surgery or those whose SBO resolved prior to the administration of water-soluble contrast were excluded from this study. The use of iEMR allowed for universal access, subsequent longitudinal follow-up, permitting evaluation of long-term outcomes with minimal loss to follow-up.

3.3. Exposure

The exposure in this study was successful water-soluble contrast

challenge which we defined as contrast reaching the colon on plain film radiography or those who opened their bowels after water-soluble contrast administration. Primary analysis compared those who achieved successful water-soluble contrast challenge compared to the individuals who still required surgical intervention. Secondary analysis observed the number of patients who were readmitted within 6 weeks with SBO despite resolution of SBO with a successful water-soluble contrast challenge.

3.4. Statistical Analysis

Data was analysed from September 2022 – January 2023. Data analysis will be undertaken with IBM SPSS Statistics for Windows Version 25.0 (IBM Corp, Armonk, NY). The outcome variables were then assessed and reported with standard parametric statistical tests after normalization of data (Figure 1).



Figure 1: Flowchart displaying inclusion/exclusion criteria

4. Results

Between January 2020 and January 2021, a total of 235 cases fulfilled our inclusion and exclusion criteria and were included for review. Of this cohort, 139 patients received Omnipaque and 96 patients received Gastrografin in line with the standardized SBO pathway. There is a total of 135 female and 100 male patients, of which 82 female and 57 male patients received Omnipaque, and 53 female and 43 male patients received Gastrografin. The mean age is 69.85 (SD 14.99) for Omnipaque and 68.51 (SD 13.46) for Gastrografin. Patients who had previous adhesive small bowel obstruction are 65 for Omnipaque, and 37 for Gastrografin group (Table 1-3).

In the Omnipaque cohort, there are a total of 112 patients who successfully passed their water-soluble contrast challenge. Ten patients in the Omnipaque cohort still needed further surgery due to lack of clinical resolution of their SBO. A total of 101 patients were discharged after resolution with conservative non-operative management with 9 patients who were readmitted with recurrent SBO, 4 of which needed ultimately needed emergent surgery. In the Gastrografin cohort, there are a total of 82 patients who successfully passed their water-soluble contrast challenge. Four patients required operative intervention lack of clinical resolution of their SBO. A total of 78 patients were discharged after resolution with conservative non-operative management, with 9 patients who were readmitted with recurrent SBO, 1 of which needed ultimately needed emergent surgery.

The length of inpatient stay of each cohort of patients were also recorded, measured in number of days. For the Omnipaque cohort, the mean length of inpatient stay is 6.62 ± 10.23 , and those who had successful non-operative management is 3.06 ± 3.54 . For the Gastrografin cohort, the mean length of inpatient stay 5.39 ± 4.68 , and those who had successful non-operative management is 3.74 ± 2.47 .

Table 1: Demographic information of Omnipaque and Gastrografin.aSBO = adhesive small bowel obstruction.

Demographic	Omnipaque	Gastrografin	P-value	
Age	69.85 ± 14.99	68.51 ± 13.46	0.25	
Female	82	53	0.564	
Male	57	43		
Previous aSBO	65	37	0.211	

Type of surgery	Omnipaque	Gastrografin	
Appendicectomy	23	28	
Cholecystectomy	19	19	
Colonic	36	30	
Small bowel	5	6	
Gastric	3	6	
Splenectomy	2	1	
Gynaecological	26	30	
Nephrectomy	1	4	
Cystoprostatectomy	0	1	
Pancreatic surgery	0	1	
Adhesiolysis	4	13	

Table 2: Types of previous surgery

Table 3: Outcomes comparing Omnipaque and Gastrografin

Category	Omnipaque	Gastrografin	P-value
Total cases	139	96	-
Successful challenge	112 (80.58%)	82 (85.42%)	0.336
Discharged without surgery	101 (72.66%)	78 (81.25%)	0.129
Readmitted within 6 weeks	9 (8.91%)	9 (11.54%)	0.601
Overall success rate	92 (66.19%)	73 (71.88%)	0.356
Mean duration of stay (days)	6.62 ± 10.23	5.39 ± 4.68	0.028
Mean duration of stay of successful group (days)	3.06 ± 3.54	3.74 ± 2.47	<.001

5. Discussion

SBO is a major cause of admission to the surgical unit. When SBO is secondary to adhesions, non-operative management is usually advocated if there is no immediate indication for emergent surgery [3,4]. The decision to employ the use of water-soluble contrast in the resolution of adhesional SBO varies between centers and several centers do not advocate their use at all. The therapeutic role of water-soluble contrast remains debatable; whilst most systemic reviews of the extant literature support the predictive role for non-operative resolution of adhesive small bowel obstruction using water-soluble [2,6-9]. There are reports of successful use of the lower osmolality agents such as Omnipaque instead of the wide-ly reported high osmolality agent Gastrografin [14-16]. Our study directly compares outcomes from both agents, and by extension, the effect of osmolality on the conservative non-operative management of adhesive SBO.

Our results suggest that there is no significant difference in the rate of success in water-soluble contrast challenge between Omnipaque or Gastrografin. There is also no statistical difference where the water-soluble contrast appears detectable in the colon on plain film radiography. Furthermore, there is also no statistically significant difference between those who required surgical management despite a successful water-soluble contrast challenge regardless of the agent used. The overall success rate is generally lower than the success rate reported in literature, but this is likely due to the inclusion of readmission data to our analysis. Once we exclude readmission rates, the non-operative management pathway shows similar success rates to the extant literature with the Omnipaque cohort having a lower (albeit non-statistically significant) in resolution of adhesional SBO when compared to Gastrografin. Both agents demonstrated statistical significance in reduced hospital length of inpatient stay when compared to operative management. This suggests that despite Omnipaque having an inferior osmolality to Gastrografin, our analysis shows that there is no statistical significance in the resolution of adhesional SBO between the agents.

6. Strengths and Limitations

A key strength of our study is robust coding and analysis of longitudinal data on a 'capture-all' medical record software (iEMR) which allowed us to monitor the evolution of adhesional SBO and assess how conservative and operative management strategies affected the management of the disease. Our comprehensive data capture also minimized loss to follow-up in the SBO cohort whilst allowing us to carefully monitor readmission data. We also took care to expand our search criteria to all cases of intestinal obstruction in an attempt to capture all cases of adhesional SBO however, errors in coding and variable quality of documentation may also mean that cases may be missed and not being recalled for analysis.

7. Conclusion

Our results suggest that the two different agents are equally useful as an adjunct in management of adhesional SBO, and furthermore, the difference in osmolality has no statistically significant effect on rates of successful water-soluble contrast challenge, readmission rate or hospital inpatient stay. Therefore, it may be prudent to use a lower osmolality water-soluble contrast agent like Omnipaque, especially as it has a superior safety profile than when compared to high osmolality agents like Gastrografin. We invite further study into this topic with larger cohort groups and multicenter experience to further inform on this important topic to increase the confidence level of our finding.

8. Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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