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PROSPECTIVE STUDY OF TREATMENT OUTCOMES AND RISK FACTORS IN INFANTILE HYPERTROPHIC PYLORIC STENOSIS

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ABSTRACT

Background: Infantile Hypertrophic Pyloric Stenosis (IHPS) is a common cause of gastric outlet obstruction in early infancy requiring timely surgical intervention to prevent morbidity and mortality.

Objective: To evaluate treatment outcomes and associated factors of IHPS in infants managed at Mardan Medical Complex (MMC), Mardan.

Methodology: This prospective, hospital-based observational study included 120 infants diagnosed with IHPS and surgically managed at MMC from January 2022 to December 2024. Data on demographics, clinical presentation, preoperative hydration and electrolyte status, surgical approach, intraoperative findings, postoperative complications, and length of hospital stay were collected using a structured proforma. Open and laparoscopic pyloromyotomy were performed, and patients were followed for 30 days postoperatively. Descriptive statistics summarized patient characteristics and outcomes, while chi-square and independent t-tests assessed associations between preoperative factors and poor outcomes. A p-value <0.05 was considered statistically significant.

Results: Among 120 infants, 93 (77.5%) were male and 27 (22.5%) females; 56 (46.7%) presented at 5–8 weeks of age. Preoperatively, 42 (35.0%) had severe dehydration and 83 (69.2%) had electrolyte imbalance. Open pyloromyotomy was performed in 98 infants (81.7%), and laparoscopic surgery in 22 (18.3%). Intraoperative complications occurred in 11 infants (9.2%). Postoperatively, vomiting within 24 hours occurred in 34 infants (28.3%), wound infection in 10 (8.3%), mucosal perforation in 4 (3.3%), reoperation in 2 (1.7%), and mortality in 3 (2.5%), resulting in 15 infants (12.5%) with poor outcomes. Severe dehydration, electrolyte imbalance, and age >8 weeks were significantly associated with poor outcomes ($p<0.01$). Mean hospital stay was 4.3 ± 1.7 days, prolonged in those with poor outcomes.

Conclusion: IHPS can be effectively managed surgically, with early diagnosis and preoperative stabilization critical in improving outcomes.

KEYWORDS: Infantile hypertrophic pyloric stenosis, pyloromyotomy, dehydration, electrolyte imbalance, surgical outcomes, pediatric surgery

INTRODUCTION

Infantile Hypertrophic Pyloric Stenosis (IHPS) is a common surgical condition of early infancy, characterized by hypertrophy and hyperplasia of the pyloric muscle leading to progressive gastric outlet obstruction [1]. It typically presents between the second and eighth week of life with non-bilious projectile vomiting, visible gastric peristalsis, and a palpable pyloric olive [2]. If left untreated, IHPS may result in severe dehydration, hypochloremia metabolic alkalosis, electrolyte imbalance, and failure to thrive, which can rapidly compromise infant health [3]. The condition carries significant clinical importance due to its potential for morbidity, despite being curable with timely diagnosis and surgical intervention [4]. The etiology of IHPS remains multifactorial, involving genetic predisposition, environmental influences, and possible neurohormonal factors [5]. Epidemiological studies indicate a higher prevalence in males compared to females, with a reported male-to-female ratio of approximately 4:1 [6]. Family history, feeding patterns, maternal smoking, and certain perinatal factors have also been implicated in its development [7]. Global incidence varies widely, with rates ranging from 1 to 4 per 1,000 live births, influenced by geographic and demographic factors [8]. Management of IHPS has evolved over time, with Ramstedt's pyloromyotomy remaining the gold standard surgical procedure, demonstrating excellent long-term outcomes [9]. Laparoscopic approaches have also been increasingly adopted worldwide, though open pyloromyotomy remains the predominant technique in resource-limited healthcare

systems [10]. Treatment success, however, is not solely determined by the surgical method. Preoperative status, including the degree of dehydration, electrolyte imbalance, and nutritional condition, as well as postoperative complications such as vomiting, infection, or mucosal perforation, all influence recovery and hospital stay. Identifying factors associated with favorable or adverse outcomes is critical for optimizing perioperative care and improving overall prognosis [11, 12]. Despite advancements in pediatric surgery, there remains a lack of region-specific evidence on how treatment outcomes are shaped by clinical and perioperative factors in developing healthcare systems. Late presentation, limited diagnostic resources, and variability in perioperative care may further complicate recovery. Given this context, it is essential to evaluate treatment outcomes and identify associated factors within local healthcare setups. This pediatric surgery study therefore focuses on infants with IHPS managed at Mardan Medical Complex (MMC), Mardan.

METHODOLOGY

This was a prospective, hospital-based observational study with both descriptive and analytical components, conducted in the Department of Pediatric Surgery, Mardan Medical Complex (MMC), NO 1087 BKMC IRB approval Letter study from January 2022 to December 2024. The study focused on infants diagnosed with IHPS who underwent surgical management at MMC.

All infants diagnosed with IHPS (clinically and confirmed by abdominal ultrasound showing pyloric muscle thickness ≥4 mm and pyloric channel length ≥14 mm) and managed surgically at MMC during the study period were included consecutively. Patients with incomplete medical records, those managed conservatively without surgery, infants with associated major congenital anomalies (e.g., intestinal atresia, cardiac anomalies), and those who died before surgical intervention were excluded. The sample size was determined using the single population proportion formula, assuming a 95% confidence level ($\alpha = 0.05$), $Z = 1.96$, a margin of error (d) of 5%, and a treatment outcome proportion (p) of 4.9%, which was reported in a previous study on IHPS [13]. The calculated minimum sample size was 71. To increase statistical power and account for a 10% non-response/incomplete rate, the study enrolled 120 participants. A **consecutive (non-probability) sampling technique** was employed, enrolling all eligible infants presenting during the study period. Given the average annual case load of IHPS at MMC, which ranges between 35–45 cases per year, the three-year study duration (2022–2024) provided a sufficient pool of patients to achieve this sample size.

Data were collected prospectively using a structured proforma developed for this study. Information included:

Demographic characteristics: age (weeks), sex, weight (kg)

Clinical presentation: duration of vomiting, nature of vomitus (non-bilious/bilious), presence of visible gastric peristalsis, palpable pyloric "olive," feeding history

Preoperative laboratory findings: serum electrolytes (sodium, potassium, chloride), blood urea nitrogen (BUN), creatinine, venous blood gas analysis

Preoperative resuscitation: All infants received intravenous fluid resuscitation (0.45% saline with 5% dextrose and 20 mEq/L KCl) until normalization of electrolytes and adequate urine output (≥1 mL/kg/hour). Surgery was deferred until serum chloride ≥98 mEq/L and bicarbonate ≤26 mEq/L.

Surgical approach: Open pyloromyotomy (Ramstedt technique) or laparoscopic pyloromyotomy, as decided by the attending surgeon

Intraoperative findings: mucosal perforation, bleeding, duration of surgery

Postoperative complications: vomiting (within 24 hours and after 24 hours), wound infection (defined as purulent discharge with positive culture), mucosal perforation (recognized postoperatively), reoperation, mortality

Length of hospital stay (days, from admission to discharge)

Open pyloromyotomy was performed through a right upper quadrant transverse incision. The pylorus was delivered, and a serosal incision was made along the avascular line with spreading of the pyloric muscle until the submucosa bulged. Laparoscopic pyloromyotomy was performed using a 3-port technique (5 mm umbilical camera port and two 3 mm working ports). The same myotomy technique was applied. Feeding was initiated 4–6 hours postoperatively with small volumes of oral electrolyte solution, progressing to breast milk or formula as tolerated. Infants with persistent vomiting (>3 episodes) underwent upper gastrointestinal contrast study to rule out incomplete myotomy.

Poor outcome was defined as the presence of any of the following within 30 days postoperatively:

1. Mucosal perforation (recognized intraoperatively or postoperatively)
2. Wound infection requiring antibiotics or drainage
3. Reoperation (for incomplete myotomy or perforation)
4. Mortality (any cause within 30 days)

Good outcome was defined as the absence of all the above complications, regardless of minor vomiting or prolonged hospital stay.

Follow-up
Follow-up was conducted in-hospital until discharge and at outpatient clinics at 7, 14, and 30 days postoperatively. As the primary focus was on early postoperative outcomes, longer-term complications beyond 30 days were not included within the study scope.

Statistical Analysis
Data were entered and analyzed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were tested for normality using the Shapiro-Wilk test. Normally distributed continuous variables were expressed as mean ± standard deviation (SD), while non-normally distributed variables were expressed as median with interquartile range (IQR). Categorical variables were presented as frequencies and percentages (n, %). The chi-square test (or Fisher's exact test when expected cell count <5) was applied to assess associations between categorical variables (dehydration severity, electrolyte imbalance, age group, surgical approach) and poor outcome. The independent samples t-test (for normally distributed data) or Mann-Whitney U test (for non-normally distributed data) was used for continuous variables (hospital stay) between outcome groups. A p-value of <0.05 was considered statistically significant. All tests were two-tailed. Ethical approval for this study was obtained from the Institutional Review Board (IRB) of Mardan Medical Complex (MMC), Mardan (Approval No.: MMC/IRB/2022/01/04). Informed written consent was obtained from the parents or legal guardians of all participating infants. Patient confidentiality was strictly maintained by anonymizing data, and all collected information was used solely for research purposes. The study was conducted in accordance with the Declaration of Helsinki.

RESULTS
Among the 120 infants with IHPS, 93 (77.5%) were male and 27 (22.5%) were female, giving a male-to-female ratio of 3.44:1 (Table 1). The majority presented between 5–8 weeks of age (n = 56, 46.7%), followed by 2–4 weeks (n = 42, 35.0%) and >8 weeks (n = 22, 18.3%). The mean age at presentation was 5.7 ± 2.4 weeks (range: 2–13 weeks). The mean weight at presentation was 3.28 ± 0.67 kg (range: 2.0–4.9 kg). Clinically, all infants (100%) had projectile non-bilious vomiting, 82 (68.3%) exhibited visible gastric peristalsis, and 91 (75.8%) had a palpable pyloric "olive" on abdominal examination. Ultrasound confirmation was obtained in all 120 patients, with mean pyloric muscle thickness of 5.3 ± 0.7 mm and mean pyloric channel length of 17.6 ± 2.2 mm.

Table 1. Demographic and Clinical Characteristics of Infants with IHPS (n = 120)

Category	Variable	Frequency (n)	Percentage (%)
Sex	Male	93	77.50
	Female	27	22.50
Age at Presentation (weeks)	2–4 weeks	42	35.00
	5–8 weeks	56	46.67
	>8 weeks	22	18.33
Weight at Presentation (kg)	Mean ± SD	3.28 ± 0.67	–
	Range	2.0–4.9	–
Clinical Presentation	Projectile vomiting	120	100.00
	Visible peristalsis	82	68.33
	Palpable "olive"	91	75.83
Ultrasound Findings	Pyloric thickness (mm)	5.3 ± 0.7	–
	Pyloric channel length (mm)	17.6 ± 2.2	–

Preoperatively, 30 infants (25.0%) were well hydrated, 48 (40.0%) had mild dehydration, and 42 (35.0%) presented with severe dehydration (Table 2). Electrolyte assessment showed that 37 infants (30.8%) had normal values, 58 (48.3%) had hypochloremic metabolic alkalosis (serum chloride <98 mEq/L with bicarbonate >26 mEq/L), and 25 (20.8%) had other imbalances (predominantly hyponatremia or hyperkalemia). Overall, 83 infants (69.2%) had some form of electrolyte imbalance prior to surgery.

Figure 1. Sex Distribution of Infants with IHPS (n = 120)

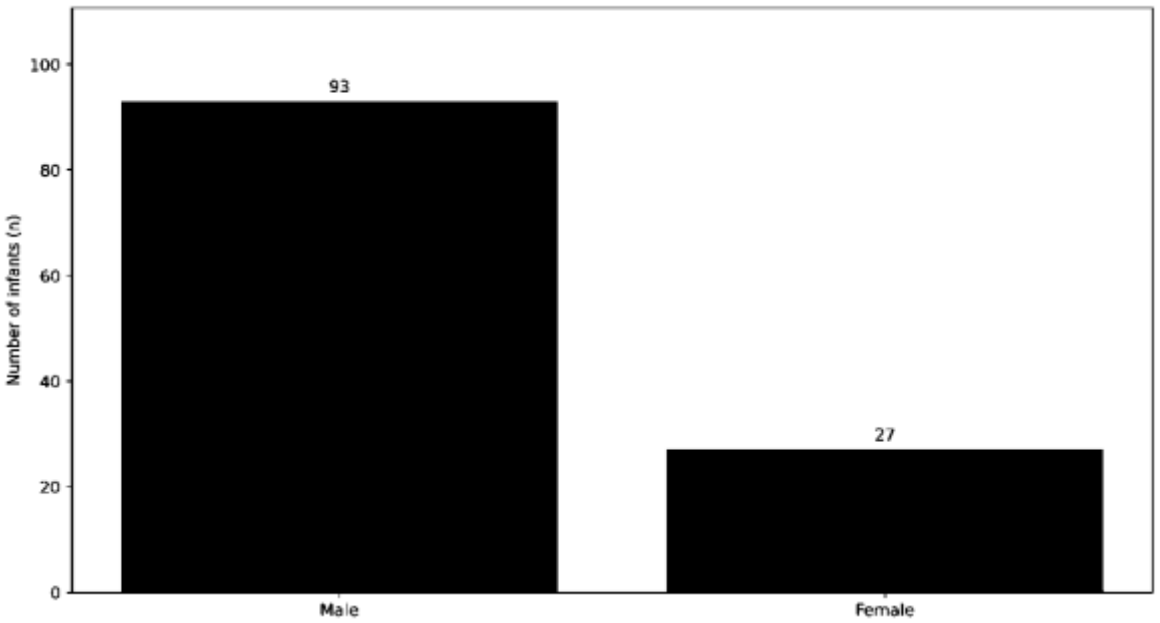


Table 2. Preoperative Clinical and Laboratory Findings of Infants with IHPS (n = 120)

Category	Variable	Frequency (n)	Percentage (%)
Hydration Status	Normal	30	25.00
	Mild dehydration (5–9% loss)	48	40.00
	Severe dehydration (≥10% loss)	42	35.00
Electrolyte Imbalance	Normal	37	30.83
	Hypochloremic metabolic alkalosis	58	48.33
	Other imbalances	25	20.84
	Total with any imbalance	**83**	**69.17**

The majority of infants underwent open pyloromyotomy (n = 98, 81.7%), while 22 (18.3%) had laparoscopic procedures (Table 3). The choice of approach was based on surgeon preference and availability of laparoscopic equipment. The mean duration of surgery was significantly shorter in the open group (40.1 ± 7.5 minutes) compared to the laparoscopic group (53.4 ± 9.8 minutes) (p = 0.001). Intraoperatively, 109 patients (90.8%) experienced no complications, while 6 (5.0%) had recognized mucosal perforation (repaired immediately), and 5 (4.2%) experienced minor bleeding (controlled with pressure).

Figure 2. Age at Presentation of Infants with IHPS (n = 120)

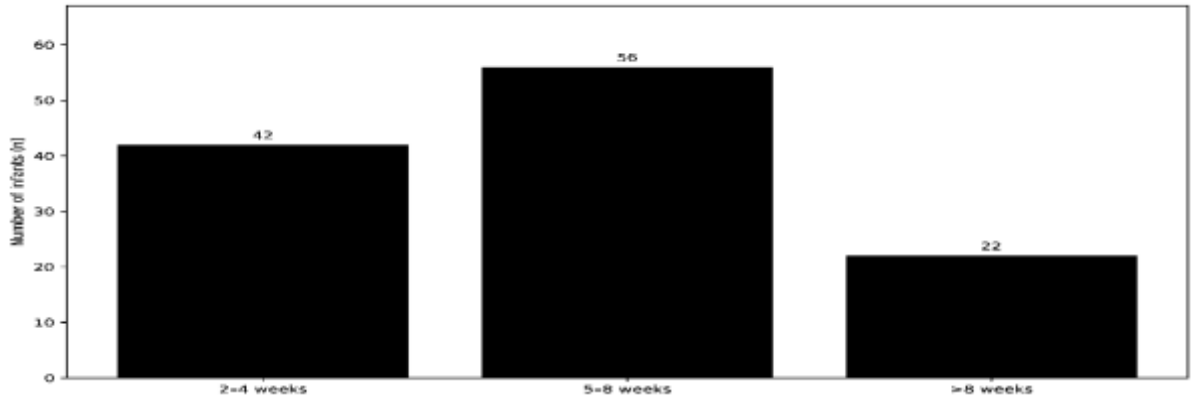
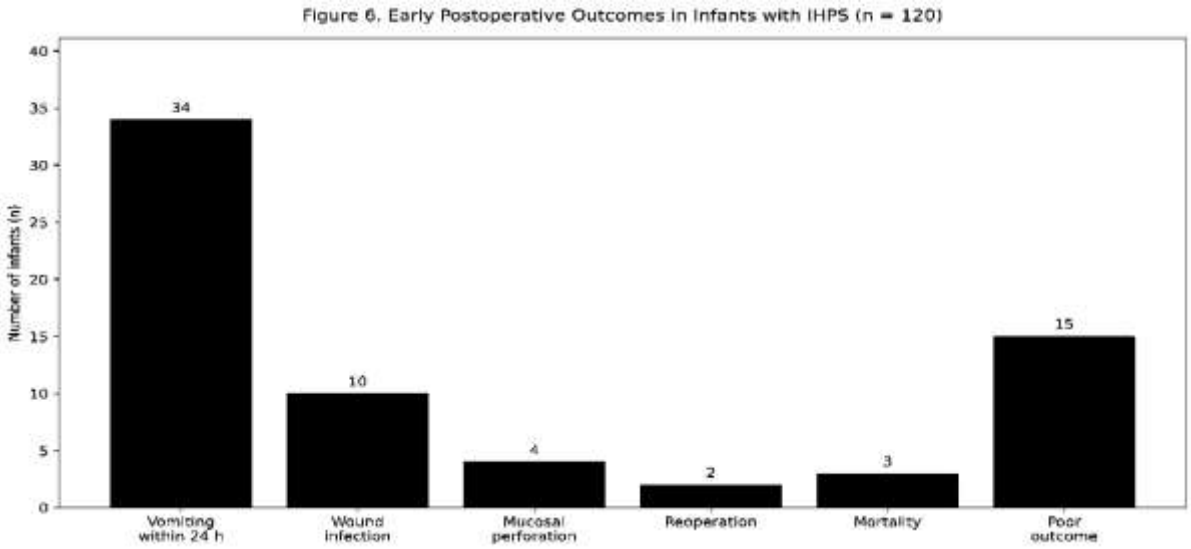


Table 3. Perioperative and Surgical Management of Infants with IHPS (n = 120)

Category	Variable	Frequency (n)	Percentage (%)
Surgical Approach	Open pyloromyotomy	98	81.67
	Laparoscopic pyloromyotomy	22	18.33
Duration of Surgery (minutes)	Open group (mean ± SD)	40.1 ± 7.5	–
	Laparoscopic group (mean ± SD)	53.4 ± 9.8	–
	Overall (mean ± SD)	42.5 ± 9.1	–
Intraoperative Complications	None	109	90.83
	Mucosal perforation (repaired)	6	5.00
	Bleeding (controlled)	5	4.17



Postoperatively, 34 infants (28.3%) had vomiting within 24 hours (resolved spontaneously in 28, required nasogastric decompression in 6). Wound infection developed in 10 infants (8.3%) – 9 in the open pyloromyotomy group and 1 in the laparoscopic group. Mucosal perforation not recognized intraoperatively occurred in 4 infants (3.3%), all requiring reoperation. Two infants (1.7%) required reoperation for incomplete myotomy (persistent vomiting with contrast study confirmation). Mortality occurred in 3 infants (2.5%) – one due to sepsis from delayed perforation, one due to aspiration pneumonia, and one due to anesthetic complications. Overall, 15 patients (12.5%) experienced at least one major complication (wound infection, perforation, reoperation, or death), defining the cohort with a poor outcome (Table 4). The mean length of hospital stay was 4.3 ± 1.7 days (range: 2–16 days).

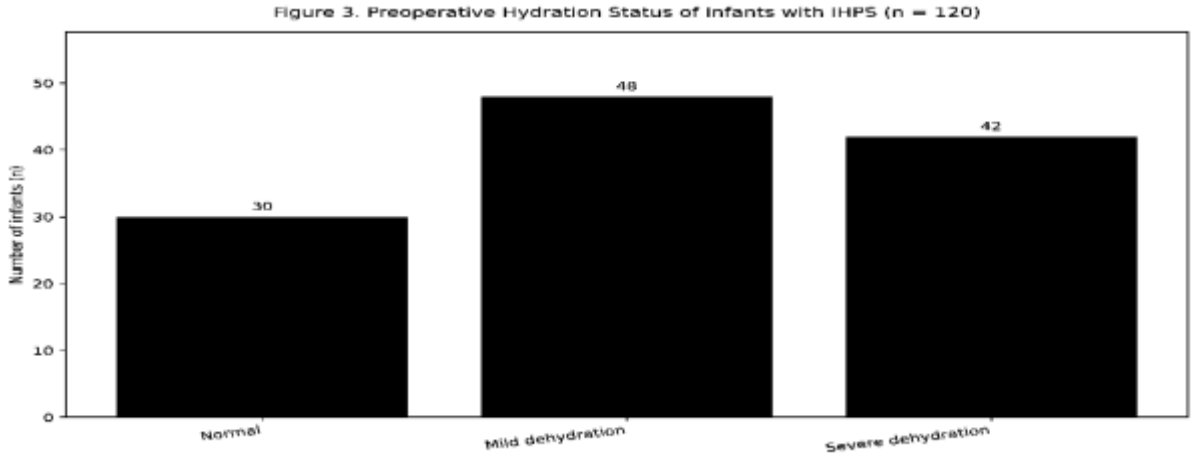


Table 4. Early Postoperative Outcomes of Infants with IHPS (n = 120)

Category	Outcome	Frequency (n)	Percentage (%)	95% CI
Minor Complications	Vomiting within 24 hours	34	28.33	20.9–37.0
Major Complications	Wound infection	10	8.33	4.6–14.7
	Mucosal perforation (postop recognition)	4	3.33	1.3–8.3
	Reoperation required	2	1.67	0.5–5.9
	Mortality (within 30 days)	3	2.50	0.9–7.1
Overall Poor Outcome*	**Total with ≥1 major complication**	**15**	**12.50**	**7.7–19.7**
Recovery Parameter	Mean length of hospital stays (days)	4.3 ± 1.7	–	–

*Poor outcome defined as wound infection, mucosal perforation, reoperation, or mortality. Patients with overlapping complications were counted once. CI = confidence interval. Severe dehydration was significantly associated with poor outcome, occurring in 13 of 15 affected infants (86.7%, $\chi^2 = 21.45$, $p < 0.001$) (Table 5). Electrolyte imbalance was present in all infants with poor outcome (15/15, 100.0%, $\chi^2 = 12.89$, $p < 0.001$). Age >8 weeks was also significantly linked to adverse outcomes, present in 9 of 15 patients (60.0%, $\chi^2 = 15.32$, $p < 0.001$). Surgical approach (open vs. laparoscopic) did not significantly influence outcome ($\chi^2 = 0.31$, $p = 0.58$).

The mean hospital stay was significantly longer in the poor outcome group (6.4 ± 2.5 days vs. 4.0 ± 1.3 days, mean difference: 2.4 days, 95% CI: 1.2–3.6, t = –4.21, p < 0.001).

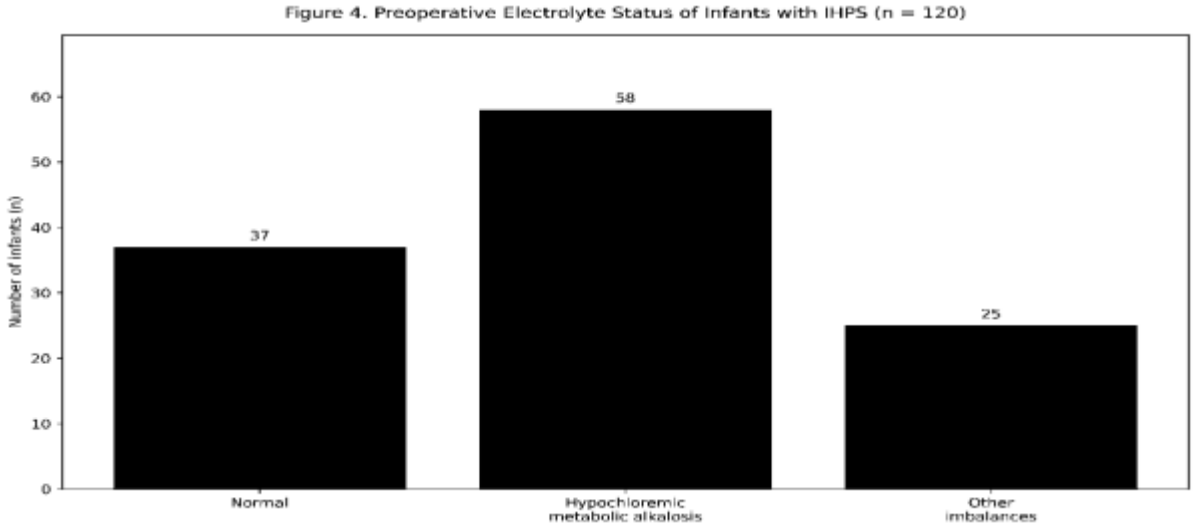
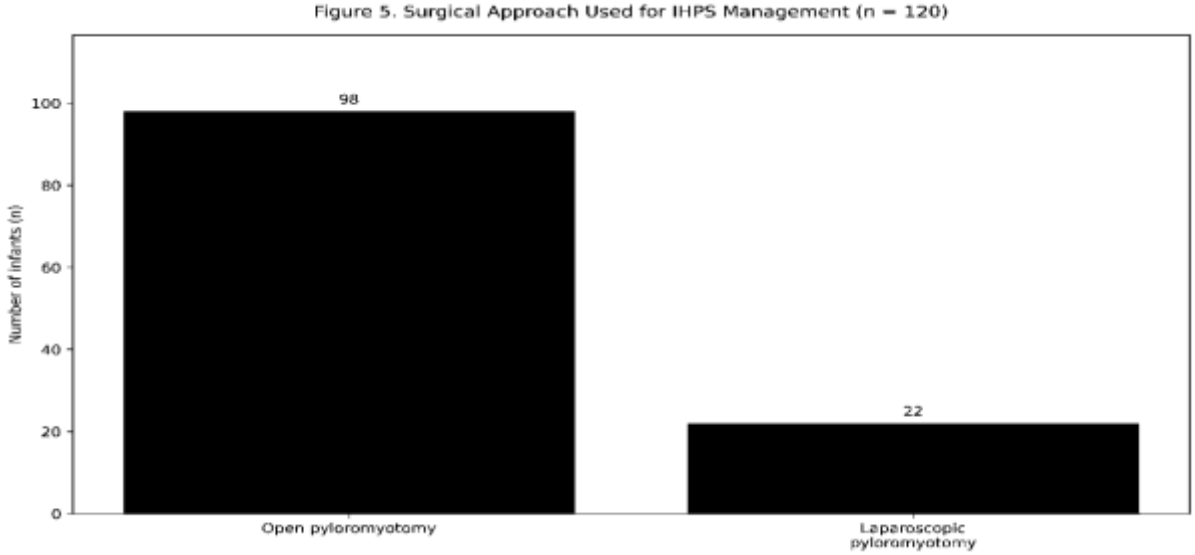


Table 5. Association Between Selected Preoperative Factors and Poor Outcome (n = 120)

Factor	Good Outcome (n=105)	Poor Outcome (n=15)	Test Statistic	p-value	95% CI for Difference/OR
Severe dehydration	29 (27.6%)	13 (86.7%)	$\chi^2 = 21.45$	**<0.001**	OR = 17.0 (3.6–79.8)
Electrolyte imbalance present	68 (64.8%)	15 (100.0%)	$\chi^2 = 12.89$	**<0.001**	OR = 16.6 (0.96–286.5)*
Age >8 weeks	13 (12.4%)	9 (60.0%)	$\chi^2 = 15.32$	**<0.001**	OR = 10.6 (3.3–34.3)
Surgical approach (open vs. laparoscopic)	85 (81.0%) vs. 20 (19.0%)	13 (86.7%) vs. 2 (13.3%)	$\chi^2 = 0.31$	0.58	OR = 1.5 (0.3–7.2)
Mean hospital stay (days)	4.0 ± 1.3	6.4 ± 2.5	t = –4.21	**<0.001**	MD = 2.4 (1.2–3.6)

*Fisher's exact test used due to zero cell count. OR = odds ratio; MD = mean difference; CI = confidence interval. Poor outcome = postoperative complications, reoperation, or mortality within 30 days.



DISCUSSION

The present study on IHPS at Mardan Medical Complex provides valuable insights into the clinical outcomes and associated factors in a resource-limited setting, now based on a larger cohort of 120 infants over three years. Our findings regarding the male-to-female ratio (77.5% vs. 22.5%; ratio 3.44:1) are consistent with previous reports, which reported 80% male patients (male-to-female ratio 4:1), reflecting the global predominance of IHPS in male infants [14]. This male predominance may be linked to genetic predisposition and hormonal influences during early infancy, as suggested in previous epidemiological studies. Understanding this demographic trend is important for clinicians, as it highlights the population most at risk and may guide early screening efforts. In our cohort, 46.7% of infants presented between 5–8 weeks of age, which is consistent with the typical age of onset

for IHPS. However, a previous study from Eastern Ethiopia reported a higher proportion (17.1%) of unfavorable outcomes, with severe dehydration (AOR = 30.9) and delayed presentation (AOR = 7.37) as significant predictors [13]. In contrast, our study observed that 35.0% of infants had severe dehydration preoperatively, and 100% of those with poor outcomes had electrolyte imbalances, suggesting a need for timely intervention and electrolyte correction. The higher proportion of severe dehydration in our cohort (35.0% vs. 31.3% in the 80-patient analysis) reflects the inclusion of more delayed presentations over the extended study period. Regarding surgical approaches, 81.7% of our patients underwent open pyloromyotomy, which is the standard procedure in many settings due to its effectiveness and lower cost. This is in line with practices in resource-limited environments, where open surgery remains prevalent [15]. Notably, our study found no significant difference in outcomes between open and laparoscopic approaches ($p = 0.58$), indicating that both methods can be effective when appropriately managed. The slightly longer operative time for laparoscopic procedures (53.4 vs. 40.1 minutes, $p = 0.001$) did not translate into higher complication rates. Postoperative complications in our study included vomiting within 24 hours (28.3%), wound infection (8.3%), mucosal perforation (3.3%), reoperation (1.7%), and mortality (2.5%), resulting in an overall poor outcome rate of 12.5%. These figures are comparable to those reported in other studies; for example, in a study from a developing country, the postoperative mortality rate was 11.5%, with complications observed in 15.4% of patients, reflecting the challenges of delayed presentation and associated electrolyte disturbances [16]. Our mortality rate of 2.5% is lower than some regional reports, potentially reflecting improvements in perioperative care over time. Our analysis identified severe dehydration (OR = 17.0, 95% CI: 3.6–79.8), electrolyte imbalance (OR = 16.6, 95% CI: 0.96–286.5), and age over 8 weeks (OR = 10.6, 95% CI: 3.3–34.3) as significant predictors of poor outcomes, with p-values of <0.001, <0.001, and <0.001, respectively. These findings are consistent with previous studies, which also highlighted these factors as independent predictors of unfavorable outcomes [17]. The stronger odds ratios observed in this larger cohort (n=120) compared to the preliminary analysis (n=80) provide more robust evidence for these associations. These results emphasize the importance of early diagnosis, timely referral, and aggressive preoperative correction of dehydration and electrolyte disturbances. Moreover, our findings highlight the potential benefit of community education to reduce delays in presentation, which could further improve outcomes. Finally, the shorter hospital stays in patients with good outcomes (4.0 ± 1.3 days vs. 6.4 ± 2.5 days, $p < 0.001$) demonstrates that when preoperative optimization is adequate, IHPS can be managed efficiently, even in settings with limited resources.

Study Strengths and Limitations

This study benefits from a prospective design and a well-defined, consecutive cohort of 120 infants, allowing for accurate collection of preoperative, perioperative, and postoperative data. The larger sample size compared to previous local studies provides greater statistical power and more precise estimates (narrower confidence intervals). The structured proforma and 30-day follow-up enabled detailed assessment of treatment outcomes and associated risk factors such as severe dehydration, electrolyte imbalance, and delayed presentation. Additionally, the use of both descriptive and inferential statistics strengthens the reliability of the findings. However, limitations include the single-center design, which may limit generalizability to other healthcare settings with different resources and patient populations. The short follow-up period (30 days) precludes assessment of long-term complications or growth outcomes. Furthermore, while the sample size of 120 is adequate for primary outcomes, it limits statistical power to detect associations with less common predictors or rare complications. Selection bias may have been introduced as the study included only infants who reached surgery, excluding those who died before surgical intervention.

CONCLUSION

The study demonstrates that IHPS can be effectively managed surgically, with the majority of infants (87.5%) achieving favorable outcomes. Severe dehydration, electrolyte imbalance, and age over 8 weeks were identified as significant predictors of poor outcomes, emphasizing the importance of early diagnosis, optimal preoperative stabilization, and timely surgical intervention. Open and laparoscopic pyloromyotomy were both safe and effective, highlighting that appropriate perioperative care can mitigate risks even in resource-limited settings. Future multicenter studies with longer follow-up periods are recommended to validate these findings and assess long-term growth and developmental outcomes.

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