



Original Article

Incision and Loop Drainage versus Conventional Incision and Drainage for Subcutaneous Abscess in Children: A Prospective Comparative Study

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Abstract

Background: Packing a freshly drained abscess cavity has long been standard practice, yet repeatedly removing that packing causes considerable distress in children and has been linked to slower healing and a higher rate of wound-related complications. Loop drainage, a packing-free alternative, has been put forward as a way to reduce this burden, though direct comparative data from South Asia have so far been limited.

Objective: To compare the clinical outcomes of incision and loop drainage with those of conventional incision and drainage in the surgical management of subcutaneous abscess in children.

Methods: This prospective comparative study was conducted in the Department of Pediatric Surgery, Dhaka Shishu (Children) Hospital. A calculated target of 84 children per arm was set; 168 children with subcutaneous abscess were enrolled and randomly allocated by lottery method in a 1:1 ratio to Group A (incision and loop drainage) or Group B (conventional incision and drainage with packing). After loss to follow-up, 120 children (60 per arm) completed the study and were analyzed. Length of incision, time to complete drainage, duration of post-operative hospital stay, number of dressings and follow-up visits, wound infection, recurrence, and scar cosmesis (assessed at six months using the Scar Cosmesis Assessment and Rating [SCAR] scale by an assessor not involved in the operation) were compared between groups. Continuous variables were compared using the unpaired t-test or the Mann-Whitney U test according to distribution, and categorical variables using the chi-square or Fisher's exact test; effect sizes with 95% confidence intervals (CIs) and exact p-values are reported, with $p < 0.05$ considered statistically significant.

Results: The two groups were comparable in age, sex, weight, abscess diameter, and anatomical site ($p > 0.05$). The mean length of incision was significantly shorter in Group A than Group B (2.3 ± 0.4 cm vs 3.3 ± 0.7 cm; mean difference -1.0 cm, 95% CI -1.21 to -0.79 , $p < 0.001$), as was the mean post-operative hospital stay (4.4 ± 1.8 vs 5.3 ± 1.3 days; mean difference -0.9 days, 95% CI -1.47 to -0.33 , $p = 0.002$), the mean number of dressings (3.6 ± 1.5 vs 5.5 ± 3.7 ; mean difference -1.9 , 95% CI -2.93 to -0.87 , $p < 0.001$), and the mean number of post-operative visits (1.6 ± 0.7 vs 2.7 ± 0.8 ; mean difference -1.1 , 95% CI -1.37 to -0.83 , $p < 0.001$). Wound infection (6.7% vs 8.3%; risk difference -1.7% , 95% CI -11.1% to $+7.8\%$, Fisher's exact $p = 1.00$) and recurrence (5.0% vs 3.3%; risk difference $+1.7\%$, 95% CI -5.5% to $+8.8\%$, Fisher's exact $p = 1.00$) did not differ significantly between groups; however, the study was underpowered for these rare outcomes, and these results should not be read as evidence of equivalence. A desirable scar (SCAR score 0) was achieved in 55.0% of Group A patients compared with none in Group B (risk difference $+55.0\%$, 95% CI 42.4% to 67.6% , Fisher's exact $p < 0.001$).

Conclusion: In selected children with uncomplicated subcutaneous abscess, incision and loop drainage was associated with a shorter incision length, shorter hospital stay, fewer dressing changes and follow-up visits, and superior scar cosmesis compared with conventional incision and drainage, without a detectable increase in the risk of wound infection or recurrence. It may represent a safe and practical alternative for the surgical management of subcutaneous abscess in this group, although adequately powered studies are needed before firm recommendations can be made.

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1. Introduction

When the body walls off an infecting organism or foreign material within a pocket of soft tissue, the resulting purulent collection is termed an abscess; this encapsulation serves a protective, host-defensive purpose by containing infection rather than allowing it to spread [1]. On examination, the lesion is typically tender, fluctuant, and accompanied by surrounding erythema and induration, occasionally with overlying cellulitis [2]. Emergency-department data from the United States illustrate how common this condition has become, with abscess-related visits roughly tripling over the decade spanning 1996 to 2005 [3]; among soft-tissue infections seen acutely, only cellulitis is encountered more often [4]. Factors that predispose to abscess formation are diverse and include a compromised immune response, the presence of a foreign body, localized tissue necrosis or ischemia, and accumulated hematoma [5]. Without adequate drainage, the consequences can extend well beyond the local site, ranging from bloodstream invasion to septic arthritis, osteomyelitis, a persistently discharging sinus tract, or overwhelming sepsis [6]. While a mix of organisms may be cultured from a given abscess, *Staphylococcus aureus* is isolated more often than any other pathogen in superficial disease [7,8].

Surgical drainage remains the cornerstone of abscess management, but considerable controversy persists regarding whether the resulting cavity should be packed, left open, or drained with an indwelling device [9]. Traditional incision and drainage involves a single incision spanning much of the abscess, blunt breakdown of loculations, saline irrigation, and packing of the cavity with ribbon gauze, followed by repeated dressing changes [10]. For children, removal of this packing is a recognized source of pain and anxiety for both the patient and caregiver, frequently requiring repeated visits to a health facility [11], and delayed or incomplete pack removal has been linked to wound infection and, rarely, toxic shock syndrome [12,13].

Incision and loop drainage has emerged over the past decade as a minimally invasive alternative that avoids packing altogether. Two small stab incisions are made at opposite poles of the abscess, the cavity is irrigated after breaking down loculations, and a soft loop – commonly fashioned from a Penrose drain, vessel loop, or the cuff of a sterile glove – is threaded through the cavity and tied loosely over the skin to maintain continuous, gravity-assisted drainage without the need for repeated packing [11,14]. Ladde et al. demonstrated that this LOOP technique is a feasible and promising alternative to traditional packed incision and drainage for pediatric skin abscess [14], and subsequent series have reported favorable outcomes with respect to hospital stay, dressing burden, and parental satisfaction [11,15].

Despite this growing body of evidence from North American settings, prospective comparisons of incision and loop drainage against conventional incision and drainage have, to our knowledge, rarely been reported from Bangladesh. Given the substantial burden of pediatric skin and soft-tissue infection in this setting and the practical advantages a packing-free technique could offer to both patients and an often resource-constrained health system, this study was designed to compare the two techniques with respect to technical, clinical, and cosmetic outcomes, with the aim of identifying an effective and less burdensome option for postoperative care of children with subcutaneous abscess.

2. Materials and Methods

2.1 Study design and setting

This hospital-based prospective comparative study was carried out in the Department of Pediatric Surgery, Dhaka Shishu (Children) Hospital, Dhaka, Bangladesh.

2.2 Participants

Children admitted with subcutaneous abscess requiring surgical drainage during the study period were eligible for inclusion. Children were excluded if the abscess diameter was less than 2 cm; if the abscess was located on the face, scalp, perianal region, palm, or sole; if it was secondary to a prior operative procedure, immunosuppressive disease, a retained foreign body, or steroid or chemotherapeutic use; if multiple abscesses were present; or if extensive surrounding cellulitis was noted.

2.3 Sample size and randomization

The minimum required sample size was calculated using the recurrence proportions reported by Ladde et al. (1.4% after loop drainage and 10.5% after conventional drainage) [14], with a two-tailed alpha of 0.05 and 80% power, which yielded a target of 84 patients per arm (168 in total). A total of 168 eligible children were therefore enrolled and randomized in a 1:1 ratio by simple random (lottery) sampling: sequentially numbered, opaque, sealed cards — half marked for loop drainage and half for

conventional drainage — were drawn from a box to allocate each enrolled child to Group A (incision and loop drainage) or Group B (conventional incision and drainage), giving 84 children per arm at randomization. During the six-month follow-up period, 48 children (28.6%) were lost to follow-up and could not be assessed for the late cosmetic and recurrence outcomes; the final analyzed sample therefore comprised 120 children, 60 in each arm (Figure 1). Because the number analyzed per arm ($n = 60$) fell below the calculated requirement of 84, the study was underpowered to detect between-group differences in the infrequent outcomes of wound infection and recurrence, and the analyses of these two outcomes are interpreted with corresponding caution.

2.4 Pre-operative evaluation

Diagnosis was established clinically by a consultant pediatric surgeon. Baseline investigations included a complete blood count, blood grouping and Rh typing, and ultrasonography of the swelling to determine the location, extent, diameter, and pus content of the abscess and to assess surrounding cellulitis. Written informed consent was obtained from the legal guardian of each child after a full explanation of the study procedures, risks, and benefits, and participation was entirely voluntary.

2.5 Operative technique

In both groups, the skin was prepared with antiseptic solution and the patient draped under general anesthesia. For Group B, a single linear incision was made across the diameter of the abscess, loculations were broken down with a hemostat, the cavity was irrigated with normal saline, and the wound was packed with ribbon gauze and dressed. For Group A, an initial stab incision was made at one pole of the abscess with a No. 11 blade; blunt dissection with a hemostat broke down loculations throughout the cavity; the hemostat was then used to tent the skin at the opposite pole, where a counter-incision was made. After saline irrigation and expression of purulent material, a loop drain fashioned from the cuff of a sterile, powder-free glove was passed through one incision and withdrawn through the other, and its two ends were tied without skin tension to permit free, continuous drainage. Pus was sent for culture and sensitivity in both groups, and a simple absorbent dressing was applied.

2.6 Post-operative care and follow-up

Children were admitted for inpatient management in accordance with unit policy for pediatric subcutaneous abscess requiring operative drainage under general anesthesia. All patients received nil-by-mouth status with intravenous fluids initially, antibiotics guided by culture and sensitivity results, and weight-appropriate analgesia (diclofenac sodium for children older than six months or paracetamol for younger infants). In Group A, caregivers were taught to inspect the dressing every two hours,

bathe the child with warm water for the first three days to promote drainage, and gently express the cavity around the loop during bathing; children returned on alternate days for review, and the loop was removed once the cavity was free of discharge and induration had resolved. In Group B, dressings and packing were changed by health personnel as needed. Children were discharged once they were afebrile, tolerating oral intake and oral antibiotics, had adequate pain control on oral analgesia, showed a clean wound with satisfactory ongoing drainage and no surrounding cellulitis, and had a caregiver competent in home wound care and loop hygiene; the same discharge criteria were applied to both groups.

Wound infection was defined as a wound that was soaked, erythematous, or discharging purulent material during the first two postoperative weeks, together with a positive wound culture; such wounds were managed with regular dressing and a 7–10-day course of culture-directed antibiotics. Recurrence was defined as the reappearance of an abscess at the same site requiring repeat drainage, intravenous antibiotics, readmission, or further surgery within 30 days of the index operation. A 30-day window was chosen because most true treatment failures and early recurrences of drained cutaneous abscesses present within the first month, whereas collections appearing later are more likely to represent new, unrelated infections; this interval is consistent with the early-outcome periods used in comparable pediatric abscess-drainage studies [14,17].

Scar cosmesis was assessed at six months postoperatively using the validated Scar Cosmesis Assessment and Rating (SCAR) scale [16], which combines six clinician-rated items (scar spread, erythema, dyspigmentation, suture/track marks, hypertrophy or atrophy, and overall impression) with two patient-reported items (itch and pain), giving a total score ranging from 0 (best) to 15 (worst). To reduce observer bias, scar assessment was performed by a single pediatric surgeon who had not participated in the index operation and who was not informed of the treatment allocation at the time of assessment. Because the two techniques leave visibly different wounds, complete masking of the assessor could not be guaranteed; this residual potential for observer bias is acknowledged as a limitation.

2.7 Outcome measures

The primary outcome measures were length of incision, time to complete drainage, duration of post-operative hospital stay, number of dressings and post-operative visits, wound infection, recurrence, and scar cosmesis score. Age, sex, and weight were recorded as independent variables.

2.8 Statistical analysis

Data were analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was examined with the Shapiro–Wilk test and inspection of histograms. Normally distributed continuous variables are presented as mean $\pm$ standard deviation and compared using the unpaired t-test, while skewed count variables (the number of dressings and post-operative visits) are additionally summarized as median (interquartile range) and compared using the Mann–Whitney U test. Categorical variables are presented as frequencies and percentages; between-group comparisons used the chi-square test, with Fisher's exact test applied when expected cell counts were small, as was the case for the rare outcomes of wound infection and recurrence. For each key outcome, the effect size — the mean difference for continuous variables and the risk difference for categorical variables — is reported together with its 95% confidence interval (CI) and the exact p-value, rather than relying on the p-value alone. A two-sided p-value of less than 0.05 was considered statistically significant. Non-significant differences, particularly for infection and recurrence, are interpreted as an absence of a demonstrated difference in the context of limited statistical power, and not as evidence of equivalence.

2.9 Ethical considerations

Ethical clearance was obtained from the institutional ethical review committee of the Bangladesh Institute of Child Health and Dhaka Shishu (Children) Hospital. Written informed consent was obtained from all parents or legal guardians, and patient autonomy, privacy, and confidentiality were maintained throughout. No financial support was received for this study, and the authors declare no conflict of interest.

3. Results

3.1 Participant flow

Of 168 children enrolled and randomized (84 per arm), 48 (28.6%) were lost to follow-up before completion of the six-month assessment — 24 in Group A and 24 in Group B — leaving 120 children (60 per arm) for final analysis (Figure 1). Loss to follow-up did not differ between the two arms (28.6% in each; Fisher's exact $p = 1.00$), and children who were lost did not differ significantly from those who completed the study in age, sex, weight, abscess diameter, or anatomical site ($p > 0.05$ for all comparisons), suggesting that attrition was unlikely to have introduced major bias in the measured baseline characteristics. The most frequent reasons for loss to follow-up were failure to attend scheduled review after clinical improvement, transfer of care to a facility nearer the family's home, and withdrawal of consent; the distribution of these reasons by group is shown in Figure

1. Figure

Figure 1. CONSORT-style participant flow diagram showing enrollment, randomization, loss to follow-up, and the numbers analyzed in each group.

3.2 Baseline characteristics

The two analyzed groups were closely matched at baseline (Table 1): mean age was 7.8 ± 3.2 years in Group A and 7.5 ± 3.6 years in Group B ($p = 0.630$), with the majority of patients in both arms aged 6–10 years. Male children predominated in both groups (55.0% in Group A and 58.3% in Group B), and mean body weight was comparable (15.8 ± 9.3 kg vs 17.6 ± 8.5 kg, $p = 0.270$). Abscess diameter and anatomical distribution were also similar between groups, with the lower extremities being the most common site (23.3% in Group A and 26.7% in Group B), followed by the chest and back, groin and buttock, and head and neck regions ($p > 0.05$ for all comparisons).

Table 1. Baseline characteristics of the two groups.

Characteristic	Group A (n=60)	Group B (n=60)	P value	Test
Age, years (mean $\pm$ SD)	7.8 ± 3.2	7.5 ± 3.6	0.630	t-test
Male sex, n (%)	33 (55.0)	35 (58.3)	>0.05	χ^2
Body weight, kg (mean $\pm$ SD)	15.8 ± 9.3	17.6 ± 8.5	0.270	t-test
Abscess diameter 3–4 cm, n (%)	29 (48.3)	27 (45.0)	0.841	χ^2
Lower-extremity site, n (%)	14 (23.3)	16 (26.7)	0.987	χ^2

3.3 Operative and recovery outcomes

With respect to operative and recovery outcomes (Table 2), the mean length of incision was significantly shorter in Group A than in Group B (2.3 ± 0.4 cm vs 3.3 ± 0.7 cm; mean difference -1.0 cm, 95% CI -1.21 to -0.79 , $p < 0.001$). Time to complete drainage did not differ significantly overall between groups, and no significant association was found between abscess diameter and time to complete drainage within either group ($p > 0.05$). The mean duration of post-operative hospital stay was significantly shorter in Group A (4.4 ± 1.8 days) than in Group B (5.3 ± 1.3 days; mean difference -0.9 days, 95% CI -1.47 to -0.33 , $p = 0.002$). Group A also required significantly fewer dressing changes (3.6 ± 1.5 vs 5.5 ± 3.7 ; mean difference -1.9 , 95% CI -2.93 to -0.87 , $p < 0.001$) and fewer post-operative follow-up visits (1.6 ± 0.7 vs 2.7 ± 0.8 ; mean difference -1.1 , 95% CI -1.37 to -0.83 , $p < 0.001$) than Group B; because these two count variables were right-skewed, they were also compared with the Mann–Whitney U test, which yielded the same conclusion.

3.4 Complications and scar cosmesis

Wound infection occurred in 4 patients (6.7%) in Group A

and 5 patients (8.3%) in Group B, a difference that was not statistically significant (risk difference -1.7% , 95% CI -11.1% to $+7.8\%$, Fisher's exact $p = 1.00$). Recurrence of abscess was observed in 3 patients (5.0%) in Group A and 2 patients (3.3%) in Group B, also not statistically significant (risk difference $+1.7\%$, 95% CI -5.5% to $+8.8\%$, Fisher's exact $p = 1.00$); the wide confidence intervals reflect the small number of events and the limited power of the study for these outcomes, so the absence of a significant difference should not be interpreted as equivalence. Among the recurrences in Group A, one occurred in a patient with an underlying infected sebaceous cyst, while the remaining two were at the same anatomical site (buttock). Scar cosmesis differed markedly between groups: 55.0% of Group A patients achieved the best possible SCAR score of 0, compared with none of the Group B patients, while the majority of Group B patients scored 1 (41.7%) or higher; this difference was statistically significant (risk difference $+55.0\%$, 95% CI 42.4% to 67.6% , Fisher's exact $p < 0.001$).

Table 2. Operative, recovery, and outcome measures. Effect sizes are expressed as the mean difference (Group A – Group B) for continuous outcomes and the risk difference (Group A – Group B) for categorical outcomes. MWU, Mann–Whitney U test.

Characteristic	Group A (n=60)	Group B (n=60)	P value	Test
Age, years (mean $\pm$ SD)	7.8 $\pm$ 3.2	7.5 $\pm$ 3.6	0.630	t-test
Male sex, n (%)	33 (55.0)	35 (58.3)	>0.05	χ^2
Body weight, kg (mean $\pm$ SD)	15.8 $\pm$ 9.3	17.6 $\pm$ 8.5	0.270	t-test
Abscess diameter 3–4 cm, n (%)	29 (48.3)	27 (45.0)	0.841	χ^2
Lower-extremity site, n (%)	14 (23.3)	16 (26.7)	0.987	χ^2

4. Discussion

The management of subcutaneous abscess in children continues to evolve, with surgeons weighing the relative merits of antibiotic therapy alone, conventional packed incision and drainage, primary closure, catheter drainage, and loop drainage [11,14,18,19]. In this prospective comparison conducted at Dhaka Shishu (Children) Hospital, incision and loop drainage was associated with a shorter incision, a shorter hospital stay, fewer dressing changes and follow-up visits, and better scar cosmesis than conventional incision and drainage, without a detectable increase in wound infection or recurrence. The age and sex distribution of the present cohort – a mean

age of approximately 7.5–7.8 years and a male predominance in both arms – is broadly consistent with, though somewhat older than, prior reports. Aprahamian et al. described a younger loop-drainage cohort with a mean age of 3.84 ± 4.5 years [17], while Ladde et al. reported a mean age of 6.2 years overall, with children in the loop-drainage group younger than those receiving conventional drainage [14]. Reported sex distributions have varied across studies, with Alder et al. and Ladde et al. both noting a slight female predominance in their cohorts [18,14], in contrast to the male predominance observed here; such variation likely reflects differences in referral patterns and population characteristics across settings rather than a true effect of treatment allocation, and in the present study these baseline characteristics did not differ significantly between groups.

Anatomical distribution in this cohort was led by the lower extremities, followed by the chest and back and the groin and buttock region, broadly mirroring the wide anatomical spread reported elsewhere, although Alder et al. and Ladde et al. both observed a particularly high proportion of buttock abscesses in their loop-drainage populations [18,14].

The significantly shorter incision required for loop drainage (2.3 ± 0.4 cm versus 3.3 ± 0.7 cm for conventional drainage) reflects the fundamental technical difference between the two approaches: loop drainage relies on two small stab incisions rather than a single incision spanning the abscess, which may in turn contribute to the more favorable cosmetic outcome observed in this study. Although the overall time to complete drainage did not differ significantly between groups, the duration of post-operative hospital stay was significantly shorter with loop drainage, a finding consistent with that of Yang et al., who reported a shorter length of stay with a continuous vacuum drainage system compared with open packed drainage [20]. The relatively long hospital stay in both arms — longer than in several North American series — should be interpreted in the context of this tertiary-referral setting, where many children are referred late with larger or more complex abscesses and where admission and discharge followed the unit criteria described in the Methods, rather than reflecting any requirement intrinsic to either drainage technique. The continuous, gravity-dependent egress of pus afforded by the loop – in contrast to the need for repeated, often delayed pack changes that can prolong wound separation and healing – offers a plausible mechanism for the shorter stay observed with loop drainage. Reported hospital-stay figures vary widely across studies (for example, Aprahamian et al. reported a markedly shorter mean stay of under one day [17], while Tsoraidis et al. reported a mean of three days [11]), likely reflecting differences in admission practices and outpatient capacity between institutions.

Patients managed with loop drainage in this study also required significantly fewer dressing changes and

post-operative visits than those managed conventionally, sparing both the child and caregiver the repeated procedures associated with pack removal and easing the burden on healthcare personnel. This finding is consistent with Aprahamian et al. and Tsoraidis et al., who both reported a relatively low number of outpatient visits in loop-drainage cohorts [17,11], and with Alder et al., who noted a longer visit schedule with traditional incision and drainage compared with catheter-based drainage [18]. Because no validated pain instrument was administered in the present study, the lower dressing and analgesic burden is best regarded as an indirect surrogate for reduced procedural discomfort rather than a directly measured reduction in pain.

Rates of wound infection were low and did not differ significantly between the two techniques (6.7% versus 8.3%). This may suggest that the omission of packing does not compromise infection control when the cavity is adequately debrided and continuously drained; however, given the small number of events and the limited power for this outcome, this comparison should be regarded as inconclusive rather than as demonstrating no difference. Likewise, recurrence rates were low and did not differ significantly between groups, broadly in keeping with the comparable recurrence rates reported by Singh et al. between loop drainage and incision with primary closure [19]. Failure to fully break down loculations during blunt dissection, rather than the drainage technique itself, is a plausible explanation for the small number of recurrences observed with loop drainage in this cohort.

The most pronounced difference between groups was in scar cosmesis, with more than half of the loop-drainage patients achieving the best possible SCAR score compared with none in the conventional drainage group. This is consistent with the smaller incision length required for loop drainage and supports its use as a cosmetically favorable option, an outcome of particular relevance in children, for whom long-term scarring carries psychosocial as well as physical significance. Because the appearance of the two wounds differs, the assessor could not be fully masked to allocation, and this should be borne in mind when interpreting the magnitude of the difference.

Taken together, these findings add to the growing body of evidence – derived largely from North American pediatric emergency and surgical practice [11,14,15,17,18] – that incision and loop drainage is a safe and less burdensome alternative to conventional packed incision and drainage, and extend this evidence to a South Asian tertiary pediatric surgical setting, from which prospective comparative data have to date been scarce.

4.1 Limitations

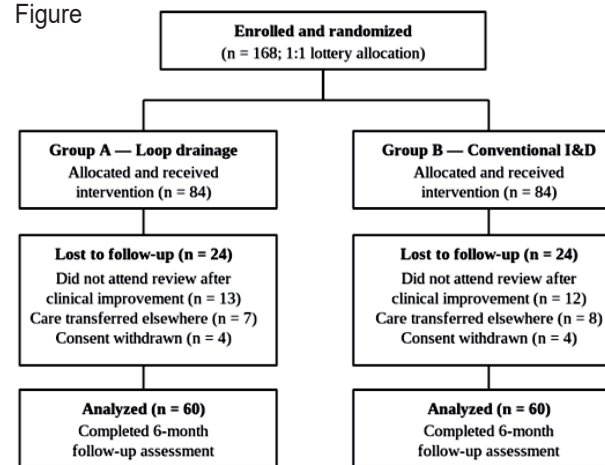
This study has several limitations. First, 48 of the 168 enrolled children (28.6%) were lost to follow-up; although loss was similar in the two arms and completers and non-completers were comparable at baseline, this degree of attrition may still

have introduced bias, and the final analyzed sample of 60 per arm fell below the calculated requirement of 84 per arm. The study was therefore underpowered to detect differences in the infrequent outcomes of wound infection and recurrence, and the absence of a statistically significant difference in these outcomes should not be interpreted as evidence of equivalence. Second, no validated pain instrument was used, so any inference about reduced pain rests on the indirect measures of dressing and analgesic burden. Third, small abscesses (diameter < 2 cm) were excluded by the treating surgeons, introducing potential selection bias, and the results apply only to selected children with uncomplicated abscesses meeting the eligibility criteria. Fourth, key procedural steps – including blind loculation breakdown, loop placement, and ultrasound assessment – are operator-dependent and were performed by multiple surgeons, which may have introduced variability in technique and outcome. Finally, the study was conducted at a single tertiary-care hospital in Dhaka city, which may limit the generalizability of these findings to other settings across Bangladesh.

5. Conclusions

In this prospective comparative study, incision and loop drainage resulted in a significantly shorter incision, shorter post-operative hospital stay, fewer dressing changes and follow-up visits, and superior scar cosmesis compared with conventional incision and drainage, with no significant difference in wound infection or recurrence. Within the limits imposed by loss to follow-up and the resulting reduced power for rare outcomes, these findings suggest that incision and loop drainage is a safe and practical alternative to conventional incision and drainage in selected children with uncomplicated subcutaneous abscess. Adequately powered, preferably multicentre studies with a validated pain assessment are warranted to confirm these findings before wider adoption can be recommended.

Figure



Total lost to follow-up: 48/168 (28.6%); loss balanced between arms ($p = 1.00$).
Completers and non-completers did not differ in baseline characteristics ($p > 0.05$).

Figure 1. CONSORT-style participant flow diagram.

Figure 1. CONSORT-style participant flow diagram showing enrollment, randomization, loss to follow-up, and the numbers analyzed in each group.

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