A Comparative Study on Use of 3% Saline Versus 0.9% Saline Nebulization in Children with Bronchiolitis

支氣管炎的兒童，使用 3% 或 0.9% 生理食鹽水進行霧化治療比較好呢?

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臨床執行方式

使用傳統式吸入蒸氣，使用0.9% Saline+支氣管擴張劑

使用PARI SINUS霧化吸入器
3%或0.9% Saline

左側：0.9% Saline
右側：3% Saline

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Introduction

- Bronchiolitis is a common clinical problem in children below 2 years.
- Studies have shown that hypertonic saline improves mucus rheologic properties (elasticity and viscosity) and accelerates mucus transport rates.
- Its inhalation increases the volume of airway surface liquid and increases rates of mucociliary clearance in normal subjects.
- A study conducted in infants with viral bronchiolitis demonstrated the effectiveness of hypertonic saline as a treatment agent.
- This double blind controlled study was undertaken to see the role of nebulized hypertonic saline in bronchiolitis and also the clinical profile in these children.

步驟 1：研究探討的問題為何？

研究族群/問題 (Population/ Problem)	Children older than 6 weeks and below 24 months with clinical presentation of bronchiolitis for the first time.
介入措施 (Intervention)	Nebulized with 0.9% saline
比較 (Comparison)	Nebulized with 3% hypertonic saline
結果 (Outcome)	1.臨床嚴重度改善 2.降低住院天數

步驟 2：研究的品質有多好？(內在效度)

招募(Recruitment) - 受試者是否具有代表性？(P.40)

我們是否知道病人族群為何(收案場所、納入 / 排除 條件)？在理想情況下，納入本研究之受試者應具有 連續性(有時為隨機取樣)，了解符合收案條件的對象且簽署同意書。

- A double blind randomized controlled trial was conducted at department of Pediatrics, Kathmandu Medical College, Sinamangal, Kathmandu for a duration of 13 months (July 2012 to August 2013).
- Children older than 6 weeks and below 24 months with clinical presentation of bronchiolitis for the first time were included in the study.
- Excluded : wheezing, chronic cardiac and pulmonary disease, immunodeficiency, respiratory failure, ventilation, inhaling the nebulized 3% hypertonic saline solution and salbutamol 12 hr before treatment, premature infants <34 weeks ,oxygen saturation below 85% on room air.
- All the children inclusion criteria were included after informed consent from the parent(s).
- The study was conducted after obtaining ethical clearance from Nepal Health Research Council.

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好？(內在效度)

分派(Allocation) - 分派方式是否隨機且具隱匿性…？ (P.40)

最理想的方式是以中央電腦進行隨機分配，此方式常用於多中心試驗，而較小型的試驗可由獨立人員(如：醫院藥師)「監督」隨機分配的過程。

- The computer generated random number was used to select the case and control group. The random numbers were kept in a sealed envelope.
- The attending nurse or physician drew the envelope and get the treatment (hypertonic saline or normal saline) accordingly.
- All eligible patients were randomly assigned to one of two groups: Group I received inhalation of 4 ml normal (0.9%) saline and group II got inhalation of 4 ml hypertonic (3%) saline. 3% saline and 0.9% saline were kept in two identical containers.
- The solutions looked similar in appearance and smell, labeled only by a code number, and placed in the research cupboard.

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好？(內在效度)

...每個組別，在研究開始時的情況是否相同？ (P.41)

若隨機分配順利，各組研究對象的條件應是相近、可互相比較的。每組研究對象的基本條件越相近越好。應有指標可確認各組研究對象之間的差異是否達到統計上顯著的差異(如 p 值)。

Table 2. Baseline characteristics of study population.

Variables	3% saline	0.9% saline	p-value
Male/Female (number)	36	36	0.789
Age (mean)(±SD)	8.61 (±5.742)	8.51(±4.24)	0.935
Antibiotic usage(number)	22	23	0.808
Steroid use(number)	5	6	0.743
Baseline score (mean) (±SD)	8.08 (±1.68)	7.36 (±1.91)	0.093
Baseline oxygen saturation (mean) (±SD)	91.47 (±1.68)	90.58 (±1.91)	0.547
Baseline respiratory rate (mean)(±SD)	59.28 (±10.48)	59.81 (±9.94)	0.827
Additional nebulization (mean)(±SD)	1.89 (±1.81)	1.77 (±2.30)	0.828

- The baseline characteristics of the two groups who received 3% saline or 0.9% saline were comparable (Table 2).
- There was no significant statistical difference in demographic characteristics of the groups of children who received 3% saline or normal saline.

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好？(內在效度)

維持(Maintenance) - 各組是否給予相同的治療？(P.42)

各研究組別之間，除了對病人的介入之外，其餘的治療應完全相同(即為了執行本研究所增加的治療、檢驗或評估應相同)。

- Children involved in our study were scheduled to receive nebulization three times in a day.
- These extra additions did not have any impact on the intervention outcome, as they were all statistically not significant ·

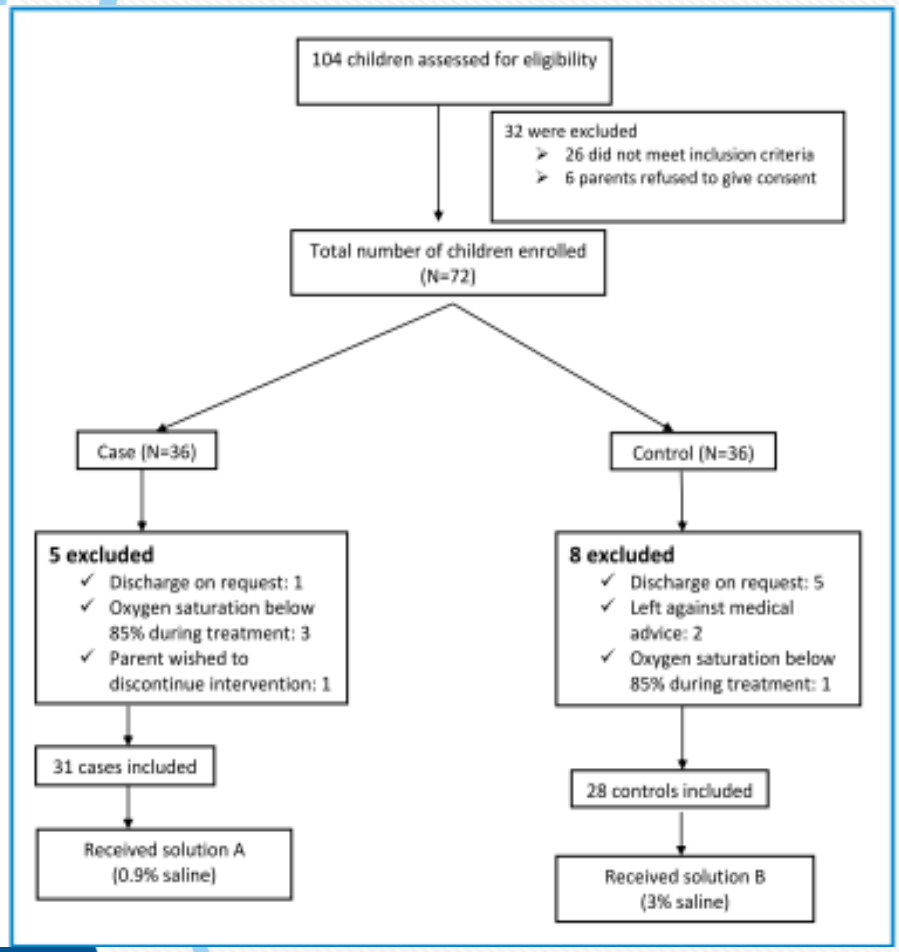
3% saline group	0.9%saline group
22 received antibiotic	23 received antibiotics
5 Received steroid (inhalational or oral)	6 received steroid (inhalational or oral)

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好？(內在效度)

...是否有足夠的追蹤(Follow up)？ (P.41)

研究中流失(無法繼續追蹤)的病人，最好少於 20%。 病人應依照隨機分配的組別進行統計分析(即「治療意向分析法」Intention – to-treat , ITT analysis)。



1. 共104 (11.26%)位嬰幼兒且被診斷為細支氣管炎
2. 32位被排除在外：26不符合納入標準、6父母拒絕
3. 兒童總數錄取(N=72)，實驗組跟對照組各36位
   - 實驗組：排除5位，接受0.9%生理鹽水共31位
   - 對照組：排除8位，接受3%生理鹽水共28位

流失率少於 20%

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好？ (內在效度)

評估(Measurement) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)？(P.

在客觀結果(如：死亡)方面，盲法的重要性較低，但在主觀結果(如：症狀或功能)方面，評估者維持盲法非常重要。

- A double blind randomized controlled trial was conducted.
- The two solutions were labeled as solution A and solution B. This labeling was done by a sister who was not involved in care to patients in the ward.
- The physicians, house staff, nurses, study personnel, and patients were blinded to treatment allocation throughout the study.

評讀結果：■是 □否 □不清楚

步驟 3：研究結果的意義為何？

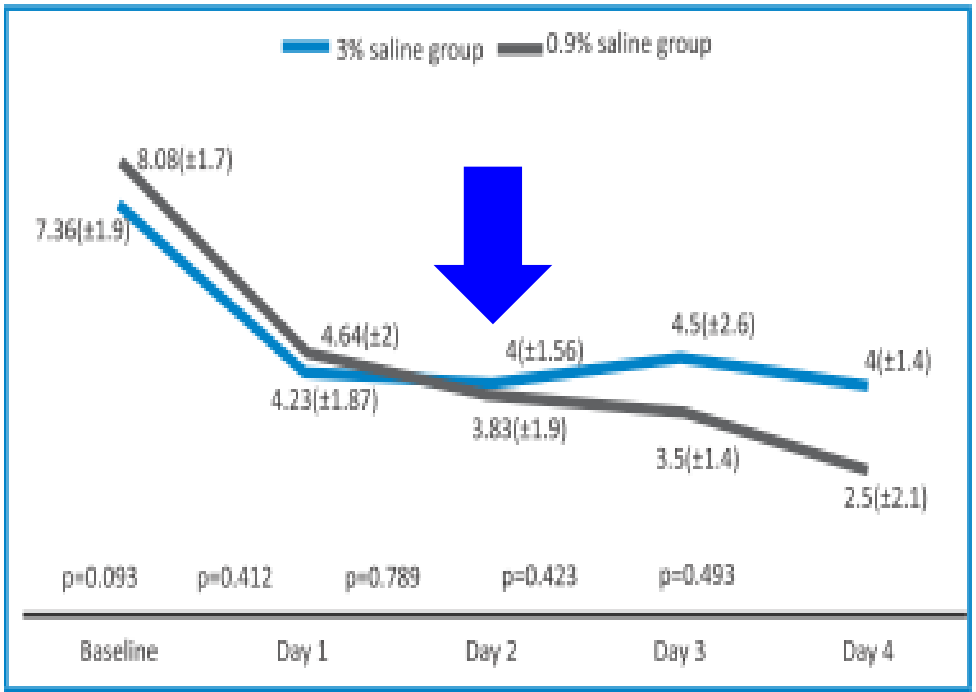


Figure 2. Graphical presentation of mean (±SD) clinical respiratory score on different days of intervention between two groups of children.

- There is a fall in clinical score between two groups after commencement of the treatment. However the fall is not statistically significant (Figure 2).

步驟 3：研究結果的意義為何？

- There are 31 and 28 patients in 0.9% saline and 3% saline group respectively who completed the treatment. The average (±SD) duration of hospital stay in these two groups were 43.60(±28.25) hours and 44.82(±23.15) hours respectively which is not statistically significant (p=0.86).
- Received 0.9% saline and 3% saline took 38.34 (±26.67) hours and 36.79 (±19.53) hours respectively to have their clinical score to fall below score of 4. This is again statistically not significant (p=0.80).
- In study group, nebulization with 3% hypertonic saline did not prove superiority to 0.9% saline for improving the bronchiolitis severity score in patients with viral bronchiolitis (p=0.801).
- It did not have any significant impact on reduction of hospital stay (p=0.859) and reduction of oxygen supplementation duration (p=0.846).

結　論

- There is no advantage of hypertonic saline over normal saline nebulization in the management as it did not reduced the duration of hospital stay, did not help in better reduction of respiratory distress score and did not decreased the oxygen requirement duration.
- This finding needs further validation using large sample size.
- In study observed that the clinical score fell very sharply in the first 48 hours of nebulization, in both the groups, even though it was statistically not significant.

討　論

是否同意支氣管炎幼兒優先使用3% Saline霧化吸入稀釋痰液，以利痰液排出？

- 同意：7人
- 懷疑：22人
- 不同意：4人

謝謝您的聆聽