

A NOVEL SILICONE ADAPTER FOR ENTERAL HYDRATION WITH BOTTLED WATER: DEVICE DESIGN AND DIRECT COST ANALYSIS

Josué Guilherme Lisboa Moura¹ , Josiele Dias da Rosa Mossmann¹ ,
Marcelo Cristiano da Silva² , Kátia Regina Bica Machado³ 

ABSTRACT

Introduction: Traditional hydration practices in hospital settings face operational challenges and high supply costs, particularly when Sterile Water for Injection (SWFI) is used enterally due to a lack of dedicated bottling infrastructure. **Objective:** To design and model a medical-grade silicone adapter enabling the direct connection of commercial bottled mineral water to enteral administration sets. **Methods:** A two-component system (threaded cap and suspension strap) was modeled using SolidWorks® and manufactured via injection-vulcanization molding with medical-grade silicone (Shore A 50). A direct material cost analysis was performed comparing bottled mineral water against SWFI. **Results:** Direct supply cost analysis demonstrated a 62.7% overall cost reduction (from US\$ 85.80 to US\$ 32.00 per patient/month) compared to SWFI, with fluid acquisition alone yielding a 77.5% saving. **Conclusion:** The developed adapter represents a technically viable proof-of-concept that reduces direct supply costs while addressing safety considerations in enteral nutrition workflows.

Keywords: *Fluid Therapy; Enteral Nutrition; Pharmaceutical Economics.*

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1 Hospital Santa Ana, Porto Alegre, RS, Brazil.

2 Micromics Medical, Novo Hamburgo, RS, Brazil.

3 Grupo Hospitalar Conceição, Porto Alegre, RS, Brazil.

Corresponding author:

Josué Guilherme Lisboa Moura
E-mail: josuemoura@hotmail.com.br
Praça Simões Lopes Neto, 175,
Teresópolis, Porto Alegre - RS,
91720-440

INTRODUCTION

Hydrating severely ill patients via the enteral route using safe water sources can be an effective strategy, particularly when oral intake is not feasible. Enteral hydration is important for maintaining fluid balance and supporting metabolic functions in these patients^{1,2}. Water used for hydration must be confirmed safe and free from contaminants, as enteral feeding may be associated with infection risk^{3,4}. In this context, the use of bottled mineral water may represent a viable alternative, as it undergoes quality control processes that ensure its safety. Distilled water can minimize these risks, as it undergoes processes that eliminate pathogens and impurities⁵. Incorporating hydration into enteral nutrition (EN) protocols can enhance tolerance and improve overall clinical outcomes^{1,2}.

To administer potable water to patients with enteral feeding tubes, it is necessary to have a specialized facility with distinct areas, such as clean and dirty zones, for proper bottling and portioning. However, this infrastructure does not match the reality of many hospitals, which face limitations in both physical space and budget. Furthermore, in emergency situations, such as natural disasters, wars, and field hospitals, these ideal conditions become even more difficult to implement, reinforcing the need for accessible solutions⁶. Given these challenges, many healthcare institutions end up using Sterile Water for Injection (SWFI), or distilled water, originally specified for parenteral use, administered via the enteral route. This is a practical, though not ideal, solution⁵.

The administration of distilled water through enteral tubes in critically ill patients is technically feasible; however, it raises concerns regarding mucosal integrity and electrolyte balance. SWFI lacks electrolytes and, when administered in large volumes, may cause dilutional hyponatremia and other

osmotic imbalances⁷. While SWFI or distilled water is frequently used as a pragmatic workaround due to immediate availability, its routine enteral use presents operational inefficiencies and financial burdens. Furthermore, using fluids packaged in parenteral-style containers for enteral hydration increases the theoretical risk of route misconnections if visual and physical safeguards are absent^{5,8}.

Given these operational and economic challenges, the research question driving this study is: Is it technically feasible to design a medical-grade silicone adapter for enteral hydration using commercial bottled water, and does it reduce direct supply costs? Thus, this study aims to describe the design, manufacturing process, and direct cost modeling of a novel enteral hydration adapter prototype.

METHODS

Device design and silicone molding

The enteral hydration device was developed using SolidWorks® software for three-dimensional modeling. The design was based on standard thread specifications for commercial polyethylene terephthalate (PET) bottled water containers (28 mm PCO 1881 neck finish). The device was designed with two main components: a threaded occlusion cap and a flexible suspension strap, both manufactured from medical-grade silicone, selected for its thermal resistance and biocompatibility. For the adapter fabrication, non-toxic silicone (Shore A 50 hardness) was used, prepared with a peroxide curing (vulcanizing) agent, 2,5-dimethyl-2,5-di-(*t*-butylperoxy)-hexane, and phthalate-free blue liquid pigment (for visual route identification). Injection-vulcanization molding was the method chosen for manufacturing the components. In brief, after being mixed with the vulcanizing agent, the silicone is injected into heated steel molds, whose geometry defines the final product shape. Inside the mold, the material is subjected to vulcanization under pressure and heat at 180 ± 10 °C. Following molding, the components underwent post-curing in a convection oven for 3 hours at 210 ± 10 °C to eliminate volatile residues^{9,10}. Manufacturing was performed by Micromics Medical (Rio Grande do Sul, Brazil) under controlled production conditions.

Interface specifications

The adapter cap features an internal threaded geometry designed to fit commercial PET bottle finishes and connect directly to standard enteral administration sets for gravity-assisted hydration¹¹. The suspension strap secures the bottle to an intravenous pole during administration⁸. The device was developed as a prototype for enteral hydration using commercially available bottled mineral water.

Direct material cost modeling

A microcosting analysis was conducted to evaluate direct material expenditures for a standard 30-day enteral hydration regimen per patient. To establish an economic modeling benchmark, a reference volume of 1000 mL/day (totaling 30 L/month) was adopted. This baseline volume represents a standardized modeling simplification rather than an individualized clinical prescription, as actual enteral fluid requirements must be tailored to each patient based on body weight, renal function, fluid losses, and underlying comorbidities¹². The financial evaluation compared two strategies: Option A (conventional practice using SWFI in 250 mL bottles) and Option B (proposed innovation using commercial bottled mineral water in 300 mL bottles fitted with the silicone adapter). The corresponding monthly container quantities, 120 bottles for Option A (4.0 units/day) and 100 bottles for Option B (3.33 units/day), were derived strictly from the arithmetic division of the 30 L baseline volume by commercially available container sizes. Unit acquisition costs were extracted from a public hospital procurement database and converted to US dollars (reference exchange rate: BRL 5.00 = US\$ 1.00). Option A included the unit fluid cost (US\$ 0.63/bottle) plus mandatory route-identification auxiliary warning labels (US\$ 0.085/label; 120 units/month = US\$ 10.20/month) required for route safety protocols. Option B incorporated both the fluid cost (US\$ 0.17/bottle) and the initial pilot acquisition cost of the silicone adapter (US\$ 0.50/unit), assuming a daily 24 h replacement protocol in compliance with standard enteral infection control guidelines (30 units/month, totaling US\$ 15.00/month). Indirect costs, including labor time, cleanroom infrastructure, and packaging waste, were excluded to isolate consumable supply expenditures.

Regulatory status

The device was formally submitted to the Brazilian Health Regulatory Agency (ANVISA) under Process No. 25351.216929/2024-85 as a Class I Medical Device. Upon technical review, ANVISA concluded that the silicone adapter does not fit the definition of a medical device under resolution No. 751/2022, officially determining the cancellation/exemption of the process due to non-applicability of sanitary registration.

RESULTS

An innovative device was developed for sealing PET bottles of mineral water, with the objective of enabling enteral administration. The product comprises two main components: a cap for sealing the container and a suspension strap, both manufactured from medical-grade silicone (Figure 1). The molded silicone

adapter achieved a tight mechanical fit onto standard PET bottle necks. Silicone was selected because of its mechanical durability and thermal resistance, properties relevant to the intended manufacturing and handling conditions¹⁰.

The direct microcosting comparison revealed substantial savings for Option B. Fluid acquisition

costs alone were 77.5% lower with bottled mineral water than with SWFI (US\$17.00 vs. US\$75.60/month). Including auxiliary safety consumables (route-identification labels for Option A; adapter replacement for Option B), total monthly expenditure fell from US\$85.80 to US\$32.00, a 62.7% overall reduction (Table 1).

Figure 1: Enteral hydration adapter

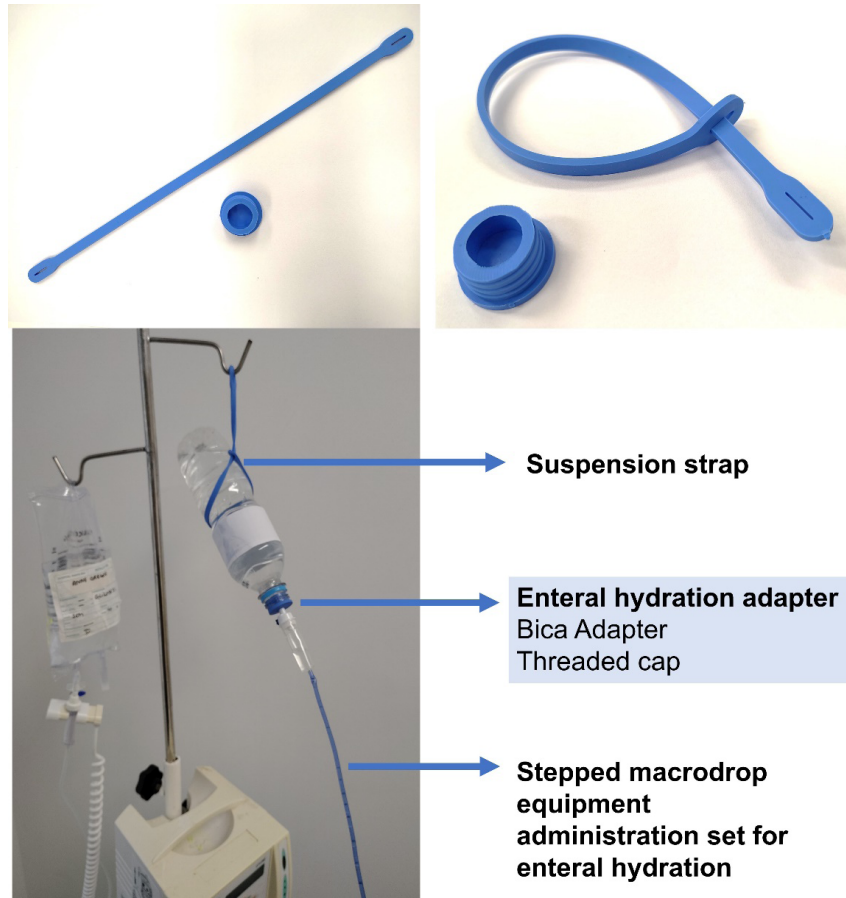


Table 1: Direct material microcosting comparison SWFI and commercial bottled mineral water with silicone adapter (30 L/month baseline model)

Parameter	Option A SWFI (250 mL) + safety labels	Option B Bottled mineral water + adapter	Difference Savings
Unit fluid acquisition cost	US\$ 0.63/bottle	US\$ 0.17/bottle	US\$ 0.46/unit
Monthly fluid expenditure	US\$ 75.60 (120 bottles)	US\$ 17.00 (100 bottles)	US\$ 58.60 (77.5% fluid savings)
Auxiliary safety consumables	US\$ 0.085/label (US\$ 10.20/month)	Not applied	- US\$ 10.20/month
Adapter unit cost and replacement	Not applied	US\$ 0.50 /unit	+ US\$ 15.00/month
Total monthly expenditure	US\$ 85.80	US\$ 32.00	US\$ 53.80 (62.7% overall savings)
Total cost per liter	US\$ 2.86/L	US\$ 1.07/L	US\$ 1.79/L reduction

DISCUSSION

The main contribution of this proof-of-concept study is the development of a simple adapter designed to connect commercially bottled mineral water directly to an enteral administration system. The design seeks to eliminate intermediate transfer or portioning steps, thereby simplifying the hydration workflow, and reducing opportunities for contamination associated with handling. The enteral hydration adapter prototype was informally named the “Bica Adapter” a regional term associated with a water outlet or faucet, chosen to facilitate quick identification and verbal communication by healthcare teams. This rationale is consistent with evidence showing that EN systems are vulnerable to microbiological contamination and that handling practices influence microbiological safety^{4,13-15}.

The blue pigmentation was incorporated as a visual identification feature to distinguish the hydration system from other hospital supplies. In conventional clinical practice, utilizing SWFI for enteral hydration poses an inherent risk of inadvertent route misconnections, as SWFI is packaged primarily for parenteral use. To optimize patient safety and mitigate this risk, traditional workflows require an auxiliary labeling process-applying printed warning labels directly to each bottle to explicitly denote exclusive enteral administration (Figure 2). While standardizing container volumes (e.g., 250 mL) optimizes logistical organization, manually labeling every bottle adds recurring consumable expenses and staff operational burden^{8,11}. Under the assumptions of the model, evaluating fluid acquisition costs alone yielded a 77.5% direct cost saving.

Figure 2: Alternative model for safe dispensation of SWFI for enteral administration



Patient and caregiver perceptions of commercial bottled water as a healthier alternative also deserve consideration, driven by beliefs regarding its natural origin and reduced contaminant levels relative to tap water¹⁶⁻¹⁹, creating a positive perception of proper hydration despite SWFI fulfilling the same physiological function. This perception is supported because bottled mineral waters undergo less processing than ultrapure waters (e.g., SWFI), which are stripped of minerals

and may not have the health benefits associated with mineral intake^{17,19,20}.

Several limitations should be acknowledged. First, the study evaluated a prototype and did not include microbiological challenge testing, quantitative leakage or mechanical integrity testing, chemical compatibility studies, or formal human-factors assessment, consequently, the specific visual contribution of the blue pigmentation to error

reduction was not experimentally investigated. Second, although patient and caregiver perceptions of bottled mineral water were discussed conceptually, the qualitative impact and visual impression on patients and families (commercial mineral water vs. SWFI) were not empirically measured. Third, the economic model was based on a single assumed monthly hydration volume and a single set of acquisition prices and therefore may vary across institutions and procurement settings. Future studies must undertake benchtop microbial validation and formal human factors usability testing and qualitative evaluations of patient and caregiver perceptions, prior to clinical deployment. Furthermore, evaluating the environmental impact, specifically the potential for clinical decarbonization and the integration of recyclable or recycled materials, represents a pathway for sustainable medical device development.

Declaration of Generative AI and AI-Assisted Technologies in the Manuscript Preparation Process

During the preparation of this work, the author(s) used Perplexity AI in order to correct grammar and improve clarity in English. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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