COME Comparative Life Cycle Assessment of Disposable and Reusable Laryngeal Mask Airways

Matthew Eckelman, PhD,* Margo Mosher,† Andres Gonzalez,† and Jodi Sherman, MD‡

BACKGROUND: Growing awareness of the negative impacts from the practice of health care on the environment and public health calls for the routine inclusion of life cycle criteria into the decision-making process of device selection. Here we present a life cycle assessment of 2 laryngeal mask airways (LMAs), a one-time-use disposable UniqueTM LMA and a 40-time-use reusable ClassicTM LMA.

METHODS: In life cycle assessment, the basis of comparison is called the "functional unit." For this report, the functional unit of the disposable and reusable LMAs was taken to be maintenance of airway patency by 40 disposable LMAs or 40 uses of 1 reusable LMA. This was a cradle-to-grave study that included inputs and outputs for the manufacture, transport, use, and waste phases of the LMAs. The environmental impacts of the 2 LMAs were estimated using SimaPro life cycle assessment software and the Building for Environmental and Economic Sustainability impact assessment method. Sensitivity and simple life cycle cost analyses were conducted to aid in interpretation of the results.

RESULTS: The reusable LMA was found to have a more favorable environmental profile than the disposable LMA as used at Yale New Haven Hospital. The most important sources of impacts for the disposable LMA were the production of polymers, packaging, and waste management, whereas for the reusable LMA, washing and sterilization dominated for most impact categories.

DISCUSSION: The differences in environmental impacts between these devices strongly favor reusable devices. These benefits must be weighed against concerns regarding transmission of infection. Health care facilities can decrease their environmental impacts by using reusable LMAs, to a lesser extent by selecting disposable LMA models that are not made of certain plastics, and by ordering in bulk from local distributors. Certain practices would further reduce the environmental impacts of reusable LMAs, such as increasing the number of devices autoclaved in a single cycle to 10 (-25% GHG emissions) and improving the energy efficiency of the autoclaving machines by 10% (-8% GHG emissions). For both environmental and cost considerations, management and operating procedures should be put in place to ensure that reusable LMAs are not discarded prematurely. (Anesth Analg 2012;114:1067–72)

riteria for the selection and purchase of medical devices typically include safety for patients and staff, efficacy and ease of use, and purchase and handling prices. On the basis of such criteria, single-use disposable medical devices are increasingly supplanting reusable devices in the United States (US) and elsewhere.¹ Although purchase and maintenance costs for disposable devices are perceived to be less than for reusables, this fails to account for indirect costs to society from the environmental impacts attributable to the entire life cycle of a device. Such an analysis is commonly performed using life cycle assessment. Growing awareness of the negative impacts from the practice of health care on the environment and public health calls for

the routine inclusion of life cycle criteria into the decisionmaking process of device selection.

The laryngeal mask airway (LMA) was introduced into clinical use in the late 1980s and approved by the Food and Drug Administration (FDA) for use in the US in 1991. The original LMA was a reusable device (Intavent International SA, Henley-on-Thames, UK). In the late 1990s, disposable LMAs became available. Several clinical trials comparing function and ease of placement demonstrated no significant difference between disposable and reusable versions,^{2–5} allowing hospitals to base purchase decisions on economic considerations alone. Decision makers have typically favored disposable LMAs because the purchase price is perceived to be less for a comparable quantity of disposable LMAs, in comparison with 1 reusable LMA with its associated labor costs for in-house reprocessing.⁶

Disposable and reusable LMAs typically differ in material composition, packaging, reuse, and cost. The differences in environmental impacts between these devices may present a compelling consideration in device selection when concern for infection transmission is not a factor. Previous studies have examined the relative environmental profiles of reusables and disposables with regard to medical textiles⁷ and anesthetic drug trays.⁸ The present study uses life cycle assessment to evaluate the life cycle impacts of disposable and reusable LMAs across several categories of environmental and human health impacts.

From the *Department of Civil and Environmental Engineering, College of Engineering, Northeastern University, Boston, MA; †School of Forestry and Environmental Studies, Yale University, New Haven, CT; ‡Department of Anesthesiology, Yale School of Medicine/Yale–New Haven Hospital, New Haven, CT.

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Address correspondence to Jodi Sherman, MD, Yale University, School of Medicine, Department of Anesthesiology, 333 Cedar Street, TMP3, New Haven, CT 06520. Address e-mail to jodi.sherman@yale.edu.

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Figure 1. Scope of the life cycle assessment for disposable and reusable laryngeal mask airways (LMAs).



Table 1. Composition Assumptions for Disposable and Reusable Largyngeal Mask Airways (LMAs)

	Disposable LMA Unique™		Reusable LMA Classic [™]	
Part	Material	Weight (g)	Material	Weight (g)
Airway tube	PVC	19.67	Silicone	20.49
Inflation line and pilot balloon	PVC	1.58	—	—
Inflation line	—	—	Silicone	1.08
Pilot balloon	—	—	Silicone	2.85
15-mm connector	Polycarbonate	5.29	Polycarbonate	2.78
Valve	Polypropylene	1.07	Polypropylene	0.72
Cuff and aperture bars	PVC	14.74	Silicone	15.34
Plastic packaging	PVC	7.61	Polypropylene	5.16
Paper packaging	Paper	2.57	Paper	6.38
Red tag "Remove Before Use"	ABS plastic	1.55	—	—
Shell for cuff	Polypropylene	8.56	—	—
Paper record card	—	—	Paper	5.17
Total LMA device	—	42.35	—	43.26
Total LMA package	—	62.64	—	59.97

PVC = polyvinyl chloride.

METHODS

We performed a life cycle assessment of 2 analogous LMAs, the disposable LMA UniqueTM and the reusable LMA $Classic^{\hat{T}M}\text{,}$ according to internationally accepted standard life cycle assessment methods (ISO 14040: 2006). The scope of our analysis, as is shown in Figure 1, includes extraction of material and energy resources, manufacturing, packaging and transport from the manufacturing site to the distribution center and the hospital, reprocessing, and eventual disposal.

In life cycle assessment, the basis of comparison is called the "functional unit." For this report, the functional unit of the disposable and reusable LMAs was taken to be maintenance of airway patency by 40 disposable LMAs or 40 uses of 1 reusable LMA.9 Data collection was specific to Yale New Haven Hospital, including device transportation, cleaning procedures and labor, energy requirements, and disposal. The life cycle assessment software package SimaPro 7.3.2 was used to conduct our analysis.¹⁰ The majority of inventory data were drawn from the ecoinvent v2.2 life cycle inventory database.¹¹ Impacts were assessed using the Building for Environmental and Economic Sustainability v4.02 impact assessment method,¹² which encompasses both environmental concerns (such as climate

change, acid rain and smog formation, water use, and ozone depletion) and human-health-related impacts (such as cancer and noncancer ailments and emission of criteria air pollutants). The human-health-related impact categories are pertinent to those developing standards for the delivery of health care. In addition, the impact categories of eutrophication (growth of microorganisms due to excess nutrients) and terrestrial ecotoxicity reflect the impacts on other species and ecosystems and have implications for public health. All of these software packages and models are in widespread use by life cycle assessment practitioners in the US and internationally.

Modeling Parameters and Assumptions

On the basis of manufacturer information and density testing, the materials used in the 2 LMAs were identified and their compositions measured using a microgram scale (Table 1). The disposable LMA consisted largely of polyvinyl chloride (PVC) plastic, and the reusable LMA consisted primarily of silicone. Where material types were unknown, proxies were assumed from relevant literature,² although more detailed material information from suppliers would permit a more robust analysis. Small components such as inks and labels on the packaging and on the sterilization

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indicator strips are expected to have negligible impacts and were excluded from the analysis. Materials were matched with appropriate life cycle inventory records from the ecoinvent database.¹¹ Injection molding was assumed for the hard plastic pieces (polycarbonate and ABS plastic) and thermoforming for the softer plastics (silicone, polypropylene, and PVC).

On the basis of information provided by the distributing company, the disposable LMA was manufactured in Hangzhou, China, and the reusable LMA was manufactured in Singapore. Both were assumed to be transported to Los Angeles, CA, by container ship, and from there by truck to the company distribution center in San Diego, CA. From San Diego, both LMAs were assumed to be transported 4700 km by truck to New Haven, CT (70% of shipments in the US are made by truck).¹³

When the devices entered use at Yale New Haven Hospital, both the disposable and the reusable LMAs were removed from their original packaging, which was discarded. A 20-mL disposable syringe was used during device placement to inflate the cuffs of both types of LMAs to ensure proper fit, and a procedure was then performed. This study assumed no difference between the devices in terms of clinical efficacy or time for placement.⁴ Disposable LMAs were discarded in regular municipal solid waste bins after use. Reusable LMAs were collected in a dirty device bin on the anesthesia cart and then reprocessed by the anesthesia technicians. After the end of their recommended lifetime, reusable LMAs were also placed in municipal solid waste containers.

Reusable LMA cleaning was observed to proceed as follows. The LMAs were first rinsed in tap water, scrubbed externally with a Hibiclens sponge and internally with a small scrub brush, and rinsed again. An estimated 1 L of tap water was used to wash and rinse 1 LMA (or 40 L over a lifetime of 40 uses). The LMA was then dried with a cotton towel. After the reusable LMA was washed and dried, it was then placed into a heat seal pouch, made of polypropylene film and paper. The LMA, within the heat seal pouch, was then placed in the steam autoclave sterilizing machine (Castle/Getinge MC 3522). Manufacturer specifications indicate 20 kWh of electricity use for a 5-minute cycle at 135°C. The autoclave was typically run with 5 LMAs, although loading varied significantly. Approximately 24 L/min of water are used by the autoclave for cooling, for a total of 960 L of water needed to sterilize an LMA 40 times. This practice meets American Society of Anesthesiologists' recommendations for infection control for equipment requiring high-level disinfection.¹⁴

After reaching the end of their useful lives, both LMAs and their respective packages entered waste management, which was modeled using US average statistics on recycling/composting, landfilling, and incineration.¹⁵ Although some incineration facilities also produce electricity, this credit is not included here.

Alternate Assumptions

There is uncertainty in several model assumptions. Alternate assumptions were used to test model sensitivity and to create bounds to aid interpretation of the results (Table 2). These included alternative routes and modes of transport from San Diego to New Haven, changes in autoclave loading practices and efficiency, and varied amounts of PVC in the disposable LMA. The number of times an LMA is reused is a particularly uncertain assumption, because there have been reports of premature disposal.¹⁶ Use in excess of the manufacturer recommended 40 times has also been reported,¹⁷ and 100 to 200 uses appears to be possible with proper handling and preuse checks.^{18–21} Here, 10, 20, 30, 60, 80, and 100 cycles are considered as alternative assumptions. Several waste management scenarios were also considered, including 100% landfilling and 100% incineration, because practices are highly location dependent. Finally, the need for manual labor in the cleaning process of reusable LMAs contributed to the costs of these LMAs. The environmental effects of labor are often omitted from life cycle assessment studies, but are included here as part of the sensitivity analysis. On the basis of observation at Yale New Haven Hospital, it takes approximately 10 minutes to conduct all cleaning processes for 1 LMA, which is equivalent to roughly \$3 in wages. Though technicians are paid regardless of whether they are cleaning LMAs or are performing some other task, these wages are nonetheless assigned to the reusable LMA on the basis of time spent. Wages are then spent on food, entertainment, transport, and other economic activities that themselves have environmental impacts. These impacts are quantified here in terms of energy use, water use, and greenhouse gas (GHG) emissions using general factors for US labor.²²

RESULTS

The life cycle impacts of the disposable and reusable LMA options are shown in Figure 2 for all impact categories, on the basis of data from Yale New Haven Hospital. Overall, reusable LMAs were found to have fewer negative environmental effects in nearly all categories, typically contributing <50% of the impacts of disposable LMAs. The largest difference in environmental impacts is seen in the impact category of carcinogenesis, in which reusable LMAs cause 5% of the impacts of disposable LMAs. The 2 LMA options are nearly equivalent in terms of eutrophication impacts, but with different contributions. The majority of eutrophication impacts from disposable LMAs are from deposition of nitrogen oxide particulates from electricity generation and waste incineration, and impacts for the reusable LMA are nearly all from wastewater used in the cleaning process. For climate change impacts specifically, the reusable LMA contributes 7.4 kg CO₂e of GHGs over its life cycle, and the equivalent 40 disposable LMAs contribute 11.3 kg CO₂e, or approximately the equivalent to burning a gallon (\sim 4 L) of gasoline.

The processes that contribute to these emissions differ markedly between the 2 LMA devices. The largest source of GHG emissions for the disposable LMAs (23%) is the production and polymerization of PVC, the main material constituent. Polycarbonate production (14%), transportation via truck (15%), thermoforming (13%), and waste disposal (11%) cause the majority of the remaining emissions. The majority (77%) of life cycle CO_2e emissions for the reusable LMA is from natural gas production and combustion to produce steam for the autoclave machine. Whereas transportation has a relatively significant GHG

Table 2. Results of Alternate Assumptions

		Disposable LMA	Reusable LMA
Alternate assumption	Impact category	(±% from base case)	(±% from base case)
Transport by rail (base case)	GHG emissions	11.3 kg CO ₂ e	7.4 kg CO ₂ e
Transport by road	GHG emissions	10.3 kg CO ₂ e (-9%)	7.4 kg CO ₂ e (0%)
Transport by air	GHG emissions	20.5 kg CO ₂ e (+81%)	7.6 kg CO ₂ e (+3%)
Autoclave (5 p) (base case)	GHG emissions	n/a	7.4 kg CO ₂ e
Individual autoclave (1 p)	GHG emissions	n/a	37.0 kg CO ₂ e (+400%)
Fully loaded autoclave (10 p)	GHG emissions	n/a	5.6 kg CO ₂ e (-25%)
Autoclave efficiency +10%	GHG emissions	n/a	6.8 kg CO ₂ e (-8%)
Current plastics (base case)	Carcinogenesis	36.8 g benzene-eq	n/a
	Noncancer	105 kg toluene-eq	n/a
+10% PVC in reusable LMA	Carcinogenesis	38.8 g benzene-eq (+2%)	n/a
	Noncancer	112 kg toluene-eq (+6%)	n/a
-10% PVC in reusable LMA	Carcinogenesis	34.8 g benzene-eq (-2%)	n/a
	Noncancer	98 kg toluene-eq (-6%)	n/a
10 reuse cycles	GHG emissions	n/a	11.4 kg CO ₂ e (+54%)
20 reuse cycles	GHG emissions	n/a	8.7 kg CO ₂ e (+18%)
30 reuse cycles	GHG emissions	n/a	7.8 kg CO ₂ e (+6%)
40 reuse cycles (base case)	GHG emissions	n/a	7.4 kg CO ₂ e
60 reuse cycles	GHG emissions	n/a	7.0 kg CO₂e (-6%)
80 reuse cycles	GHG emissions	n/a	6.7 kg CO ₂ e (-9%)
100 reuse cycles	GHG emissions	n/a	6.6 kg CO ₂ e (-11%)
Waste US average (base case)	GHG emissions	11.3 kg CO ₂ e	7.4 kg CO ₂ e
	Criteria air pollutants	0.81 microDALYs	0.28 microDALYs
Waste 100% landfilling	GHG emissions	10.5 kg CO ₂ e (-7%)	7.4 kg CO ₂ e (0%)
	Criteria air pollutants	0.86 microDALYs (-2%)	0.28 microDALYs (0%)
Waste 100% incineration	GHG emissions	14.5 kg CO ₂ e (+28%)	7.5 kg CO ₂ e (+1%)
	Criteria air pollutants	1.34 microDALYs (+7%)	0.28 microDALYs (0%)
Exclude labor (base case)	GHG emissions	n/a	7.4 kg CO ₂ e
	Water use	n/a	960 L
Include labor	GHG emissions	n/a	7.7 kg CO ₂ e (+7%)
	Water use	n/a	1008 L (+5%)

PVC = polyvinyl chloride; LMA = laryngeal mask airway; GHG = greenhouse gas; US = United States; n/a = not applicable.



Figure 2. Comparative environmental and human health (HH) impacts for disposable and reusable laryngeal mask airways (LMA), Building for Environmental and Economic Sustainability (BEES) impact assessment method.

impact for the disposable LMAs, by comparison the transportation of reusable LMAs has little impact on GHG emissions, because 40 disposable LMAs must be shipped to provide an equivalent function to 1 reusable LMA.

Considering human health concerns, the majority (60%) of impacts for the disposable LMA is due to the production of polymers, PVC in particular, with emissions from incineration contributing another 15%. The largest sources of

both cancer and noncancer impacts for the reusable LMA are from emissions from waste management (35%), the mining and production of metals to build wastewater treatment infrastructure (25%), and the bleaching of packaging paper and the card insert (20%). Criteria air pollutants arise for the disposable LMA primarily from the production of ethylene (a polymer precursor) and the combustion of natural gas throughout the system, and for the reusable LMA from the combustion of fossil fuels to produce steam and electricity.

Table 2 shows the results of alternate assumption on the overall results. The effect of alternate transport modes was quite small for the reusable LMA but quite significant for the disposable LMAs, leading to a large increase in GHG emissions in particular from air freight. Individually autoclaving the reusable LMA (because of stock shortages, for example) increased life cycle GHG emissions by >400%, whereas loading with 10 LMAs per cycle decreased emissions by nearly 25%. The more capital-intensive option of increasing the energy efficiency of the autoclave machines by 10% decreases GHG emissions by 8%. Because the human health impacts of the disposable LMAs are dominated by plastics, increasing the amount of PVC by 10% leads to a significant (>5%) increase in cancer and noncancer effects. Premature disposal of reusable LMAs has significant environmental impacts (as well as costs, discussed below). At an average of 10 reuse cycles, GHG impacts increase by >50%, and this is the break-even point at which the GHG emissions from reusable and disposable LMAs are essentially equal. This break-even point will

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change depending on the category of environmental impact being considered. At 20 reuse cycles,¹⁶ the results indicate an increase in emissions of nearly 20%. On the other hand, extending the number of uses to 80 (doubling the lifetime) reduces GHG emissions by 9%. For waste management, switching from 100% incineration to 100% landfilling typically reduced impacts across all categories by 5%–10%, with the national average scenario results decreasing in between. Finally, inclusion of the environmental impacts of labor for cleaning (from wages spent on goods and services) only nominally increases the total GHG and water impacts of reusable LMAs.

DISCUSSION

These results suggest that the reusable LMA ClassicTM has fewer life cycle impacts in comparison with the disposable LMA UniqueTM at Yale New Haven Hospital, across several categories of concern. This reflects the equivalence between 40 disposable LMAs and their associated materials, waste, and 40 uses of 1 reusable LMA. Additionally, the PVC-dominated material composition of the disposable LMA and associated packaging added significantly to its impacts.

Disposable LMAs are made largely from PVC plastic, which is associated with a number of health concerns that are gaining increased attention.²³ Historic efforts to minimize routine medical incineration resulted in the 1998 Memorandum of Understanding between the American Hospital Association and the US Environmental Protection Agency, largely on the basis of recognition of the potential carcinogenic effects of burning PVC plastics. In addition, although this life cycle assessment study did not analyze health impacts during use of an LMA, intraoperative exposure to diethylhexyl phthalate (DEHP) is of some concern. DEHP is a plasticizer routinely added to impart flexibility to PVC-based products, such as IV bags, tubing, and endotracheal tubes. LMAs may be composed of 40%DEHP by weight. DEHP leaches out upon exposure to heat and lipids, as would be the case in contact with mucous membranes. The Environmental Protection Agency classifies DEHP as a probable carcinogen, and as a possible endocrine disrupter.²⁴ The FDA issued an advisory in 2002 recommending steps be taken to reduce the risk of exposure to DEHP in certain populations.²⁵ There is enough evidence of reproductive and developmental toxicant effects from DEHP for the FDA to recommend alternatives for patients deemed at high risk, namely infants, toddlers, and pregnant and lactating women. Reusable LMAs in general appear to be made largely of silicone, lacking these same concerns for PVC/DEHP.

Despite the overall lower impacts of the reusable LMA, there are still several ways that its environmental profile could be improved, as suggested by the results shown in Table 2. The main causes of the reusable LMA's environmental impacts are the steam used in the autoclave sterilizing machine and, to a lesser extent, the wastewater generated from washing the LMAs. Each time the steam autoclave machine conducts a sterilizing cycle, a large amount of energy is used to heat the steam. The fewer LMAs placed in the autoclave, the larger the impacts on GHG emissions and global warming on each individual unit. Conversely, impacts can be reduced by autoclaving more LMAs at once or with other equipment with similar decontamination requirements. Upgrading to a new, energy-efficient autoclave machine leads to a nearly equal reduction in life cycle GHG emissions and may be considered particularly in instances in which older equipment is being used.

The results also suggest effective procurement strategies for reducing the impacts of disposable LMAs where they are selected. The majority of life cycle human health impacts of disposable LMAs are caused by PVC use in packaging and the device itself. Choosing models that use alternate materials is recommended, particularly because the American Medical Association is urging hospitals and health systems to reduce their use of PVC products, especially those containing DEHP.²⁶ The shipment of LMAs by air also greatly increased overall impacts, pointing to a strategy of bulk ordering from local distributors well in advance of use, and avoiding overnight shipment whenever possible. This points to the need for effective inventory control, which is also critical for the reusable devices because there needs to be a sufficient number clean and on hand while another batch is undergoing cleaning, sterilization, and cooling. Convenience is a potential advantage for disposable LMAs, and facilities that use reusable LMAs must ensure that a variety of sizes are always available when needed. Where regulations permit, disposal of LMArelated waste as regular municipal waste, as opposed to biohazardous waste, should also reduce the adverse health effects stemming from medical waste incineration.

Despite manufacturer-recommended cleaning processes, and various modifications thereof, proteinaceous material may remain on reusable LMAs.²⁷ Of particular concern, these residues may expose patients to prions causing transmissible spongiform encephalopathy, Creutzfeldt-Jakob disease. Iatrogenic transmission of the Creutzfeldt-Jakob disease agent has been reported in >250 patients worldwide, and 6 of these were linked to the use of contaminated equipment, all of which were neurosurgical related. All of these equipmentrelated cases occurred before the routine implementation of sterilization procedures currently used in health care facilities. No such cases have been reported since 1976.^a There is no reported case of iatrogenic infection of any type linked to a reusable LMA. Despite this, a general perception is that reusable LMAs possess a safety profile inferior to that of disposable LMAs, thus contributing to the proliferation of the latter. Select patients who are highly infective warrant the choice of disposable devices; however, data do not support selecting disposables for all patients to avoid any possible risk of infection.

Current LMA procurement decisions are typically based on perceived costs. A complete life cycle cost analysis would complement the life cycle assessment results shown here; however, a simple analysis reveals that, assuming full utilization, a \$200 reusable LMA costs \$5 per use, plus \$3 per cleaning for a unit cost of \$8, excluding utility and hospital overhead costs. The unit cost of disposable LMAs is 20% higher at approximately \$9.60 per unit. If the

^{*a*} Centers for Disease Control. Questions and Answers: Creutzfeldt–Jakob Disease Infection-Control Practices. Atlanta, 2012. Available at: http://www.cdc.gov/ncidod/dvrd/cjd/qa_cjd_infection_control.htm.

reusable LMA is discarded prematurely, e.g., after 20 uses,¹⁶ the unit cost increases to \$13 per unit, but decreases to \$5.50 if the lifetime can be extended to 80 uses. Facilities that select reusable devices should implement inventory and operating procedures that ensure that devices are reused to the greatest possible extent.

In addition to traditional criteria for the selection and purchase of medical devices that include safety, efficacy, and cost, growing awareness of the negative impacts from the practice of health care on the environment and public health calls for the routine inclusion of life cycle criteria into the product selection process. Differences in environmental impacts between devices may present a compelling consideration in their selection. Health care facilities can decrease their environmental impacts by using reusable LMAs, by selecting disposable LMA models that are not made of certain plastics, and by ordering in bulk from local distributors. The life cycle assessment results shown here allow clinicians and health care administrators to understand the balance between direct benefits of a given LMA choice to local patient care and the environmental and human health impacts of that choice that occur far from the operating room.

DISCLOSURES

Name: Matthew Eckelman, PhD.

Contribution: This author helped design the study, analyze the data, and prepare the manuscript.

Name: Margo Mosher.

Contribution: This author helped conduct the study and analyze the data.

Name: Andres Gonzalez.

Contribution: This author helped conduct the study and analyze the data.

Name: Jodi Sherman, MD.

Contribution: This author helped design the study and prepare the manuscript.

This manuscript was handled by: Steven L. Shafer, MD.

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