Title: Cost Effectiveness of Laminar Flow Systems for Total Shoulder Arthroplasty: Filtering Money from the OR?

Running Title: Laminar flow cost effectiveness

Keywords: Laminar flow; Total Shoulder Arthroplasty; Laminar flow efficacy; Laminar flow cost effectiveness; Cost effectiveness; Sensitivity analysis

Abstract

Background

Laminar flow ventilation systems were developed to reduce surgical contamination in joint arthroplasty to avoid periprosthetic joint infection (PJI). The goals of this study are to evaluate the cost-effectiveness and economic viability of installing and maintaining a laminar flow system in an operating room.

Methods

A Monte Carlo simulation was used to evaluate the cost effectiveness of laminar flow. The variables included were cost to treat PJI, incidence of PJI, cost of laminar flow, years of operating room use, and arthroplasty volume as the dependent variable.

Results

Laminar flow would be financially-justified when 1,217 (SD: 319) TSA cases are performed annually with assumed 10% reduction in PJI from laminar flow and 487 (SD: 127) with assumed 25% reduction. In a high volume OR, laminar flow costs $25.24 per case (assuming 10% reduction) and $8.24 per case (assuming 25% reduction). Laminar flow would need to reduce the incidence of PJI by 35.1% (SD: 9.1) to be a cost-effective strategy.

Conclusion

This analysis demonstrates the substantial arthroplasty volume and large reduction in PJI rates required to justify the installation and maintenance costs of this technology. This high cost of implementation should be considered prior to installing laminar flow systems.

Level of Evidence: Economic Decision Analysis Level II

Introduction

As the number of total shoulder arthroplasty (TSA) cases performed increases each year, there is an increased focus on cost reduction and value based care.(1,2) Periprosthetic joint infection (PJI) of the shoulder has a reported incidence of approximately 1% and is a large driver of unexpected cost and patient morbidity.(3–5) While a gold standard for shoulder PJI treatment has yet to be identified, treatment typically requires hospitalization, surgical intervention, and long-term intravenous and oral antibiotics. In addition to the associated health-care costs, shoulder PJI results in societal costs from lost work, decreased functional status, and associated mortality cannot be ignored.(6)

In the development of major joint arthroplasty, Sir John Charnley appreciated the significant burden of PJI.(7) At that time, Charnley identified and adopted numerous measures for the prevention of infection.(8) Ultimately, he concluded that utilizing air cleanliness and laminar flow technology created a large reduction in the risk of PJI from 8.9% to 1.3%.(9) As total joint arthroplasty was adopted internationally, the principle of laminar flow in operating rooms was replicated and is still used a half-century later. However, in recent systematic reviews and registry studies, clinical reduction of PJI rates have not been observed with utilization of laminar flow.(10,11) Furthermore, the implementation of laminar flow requires substantial capital costs and complicates efficient scheduling of TSA cases by limiting the available operating rooms. Therefore, this break-even cost analysis was undertaken to identify the necessary TSA volume and efficacy in PJI reduction to justify the installation and use of laminar flow.

Methods

A Monte Carlo break-even cost-analysis was used to determine the required efficacy of laminar flow in reducing the incidence of PJI and the annual arthroplasty volume necessary for laminar flow utilization to be a cost-effective strategy in PJI reduction. The model was a basic life-cycle cost analysis utilizing net present value adjustments of future savings. The variables included in this formula were cost to treat PJI, baseline risk of PJI, cost of installation and maintenance of laminar flow, years of operating room use, efficacy of laminar flow in decreasing PJI, and arthroplasty volume (Figure 1). By solving the equation for the desired variable (TSA volume, PJI efficacy, etc.), simulated results providing break-even cost could be determined (Figure 2).

To solve for the dependent variables (laminar flow efficacy and arthroplasty volume), we established the known values for the remaining variables listed above (Table 1). Installation and annual maintenance cost estimates were provided from this institution’s experience. The cost to treat PJI was gathered from three separate articles detailing the cost of treatment.(3–5) As the three studies identified from literature search had variable cost data and sample sizes, the cost data used for the equation was weighted by sample size. Similarly, the risk of PJI was defined by findings from a large national dataset over multiple years.(5) The risk of PJI for each year was weighted by the number of TSA’s performed within that year. The longevity of use of a filtration system is highly dependent on the continued maintenance of the equipment, but for the purposes of this study we estimated that time period to be 20 years. There is potential for significant variation in the discount rate between institutions depending upon their weighted average cost of capital for funding projects. For this analysis, we used the local currency cost of capital as provided by New York University Stern School of Business from a review of United

States hospitals and healthcare facilities. For smaller firms, or those in financial distress, cost of capital may be higher.

Due to the uncertainty in many of these variables, a Monte Carlo simulation was used when solving for the primary outcomes. From this the mean and standard deviation of the findings are reported. First, we determined the average cost of operating laminar flow per case for increasing TSA volume. Second, we solved the break-even cost formula for arthroplasty volume and performed a Monte Carlo simulation at the defined increments of laminar flow efficacy. This provided a minimum number of annual TSA cases necessary to justify laminar flow installation at various rates of PJI reduction of PJI. Third, we performed a Monte Carlo simulation to determine the efficacy of laminar flow in reducing PJI needed to justify the installation cost of this system at our institution. We used the average annual case volume in our busiest operating room (350 cases) to calculate this efficacy. We then solved the break-even cost equation for installation costs. We used a Monte Carlo simulation to calculate the maximum laminar flow installation cost for theoretical for efficacy in the ability of laminar flow to reduce the rate of PJI in TSA. We made the estimates with two assumed rates of PJI reduction, 10% and 25% efficacy (reduction in rate of PJI). Due to the low rate of PJI in TSA and the multifactorial nature of its causes, finding the true efficacy of laminar flow requires a very large volume of cases, therefore these numbers were used as estimates to calculate is cost value. For each calculation, sensitivity analysis was performed to determine the contribution of each variable to outcome variance. Simulations were performed in YASAI (2.6, Rutgers University, Piscataway, NJ).

Results

The cost of laminar flow per case decreased exponentially with increasing number of annual arthroplasties: $139.2 (standard deviation [SD]: 24.4) per case for 100 TSA cases annually, decreasing to $27.8 (SD: 4.9) per case for 500 TSA cases annually (Figure 3). Assuming laminar flow provided a ten-percent reduction in the rate of PJI, installation and maintenance of a system would be economically viable when 1,216.9 (SD: 318.5) TSA cases are performed in a single operating room (OR) annually (Figure 4). The volume threshold decreased to 486.8 (SD: 127.4) TSA cases with an assumed PJI reduction of 25%.

Using this institution's average of 350 cases in the highest volume OR, installation and continued maintenance of laminar flow cost $129,534 (SD: 33,038; $25.24 per case) assuming a reduced PJI incidence of 10% and $41,084 (SD: 64,036; $8.24 per case) for an assumed reduction of 25%, even after adjusting for savings from reduced PJI.

For laminar flow technology to be considered cost-effective based on our institution's current surgical volume, installation costs would need to be reduced by 92.6% to $10,345.79 (SD: 23,827) assuming a ten-percent reduction in the incidence of PJI from laminar flow use. Alternatively, assuming a 25% reduction in PJI the installation cost would need to be reduced by 28.7% to $99,794 (SD: 56,776). Lastly, at the current pricing, laminar flow technology would need to demonstrate a reduction of PJI by 35.1% (SD: 9.1) to be a cost-effective strategy (Table 2).

Discussion

PJI following TSA is a significant complication that is costly to treat and can result in substantial patient morbidity.(12) Recent analyses have shown implant-related infection to be the most common complication following both anatomic and reverse TSA, and the most common surgical cause for readmission within 90-days.(13,14) As such, many attempts have been made to minimize the risk of PJI following TSA, including the use of laminar flow to improve operating room air cleanliness. While Charnley et al. demonstrated significantly decreased rates of PJI following total hip arthroplasty after the implementation of laminar flow,(9) more recent analyses have not found a difference.(10,11) As more efficient surgical settings are erected, the necessity of this expensive technology is called into question. Therefore, the purpose of this study was to perform a cost-analysis of laminar flow installation and maintenance with regards to reduction of PJI.

The convincing findings of this cost analysis must be weighted by the study's limitations. First, it was necessary to make assumptions regarding some of the variables in formulating this cost-analysis, most specifically operating room longevity. We attempted to overcome this limitation by using the annual maintenance cost of laminar flow systems and using the Monte Carlo simulation to provide margins-of-error accounting for this uncertainty. Second, the scope of this study does not address the social or societal impacts of PJI. For this analysis, as the institutions bear the cost of installation and maintenance of air filtration systems, the scope for the cost of PJI is narrowed to the institutional costs of subsequent treatment. However, if considering patient quality-of-life and cost to society from lost work-time, the necessary efficacy and TSA volume needed to justify laminar flow may be substantially decreased. Lastly, this study does not further the evidence regarding the effect of laminar flow on the rate of PJI.

Despite these limitations, this study did demonstrate the substantial cost of laminar flow installation. Unfortunately, the evidence does not suggest that this cost is justified. Although Charnley demonstrated a significant reduction in PJI with the introduction of clean-air systems, more recent analyses—involving over one-hundred thousand patients—have not demonstrated a decreased rate of PJI with laminar flow.(10,11) In actuality, Hooper et al(11) and Gastmeier et al(10) found that the use of laminar flow increased the rate of PJI. While the methodologies of these studies have limitations, the increased rate of PJI is potentially explained by obstruction of laminar flow from overhead theater lights leading to eddies of contaminated air above the surgical field, and possible introduction of hypothermia due to large volumes of air through the wound bed.(15,16)

This study found that a minimum of 1,261.9 and 486.8 TSA annually would be necessary for laminar flow to be cost-effective for 10% and 25% reduction in PJI, respectively. Even at this high-volume shoulder institution, laminar flow would need to provide a 35.1% reduction in PJI to be economically viable. This presents a significant hurdle for this technology. First, it is unlikely that laminar flow application will be optimally utilized in most operating suites. In his initial review Charnley stated “perfect illumination of the surgical area takes precedence over perfection of laminar flow.”(8) Today this reality remains unchanged. Second, laminar flow is designed to prevent contamination of the wound from contaminated air. Approximately one-third of shoulder PJI is secondary to *Propionibacterium acnes* (*P. acnes*).(17) *P. acnes* likely contaminates the surgical wound directly from the skin, upon incision.(18) Third, some PJI present in a delayed fashion.(14,19) While it is possible that bacteria introduced into the surgical wound at the time of surgery may remain dormant until much later,(20) it is more probable that the majority of these late presenting infections are via hematogenous introduction.

Conclusion

In summary, laminar flow remains a widely-used technology in TSA despite conflicting evidence. This analysis illuminated the substantial cost necessary to implement laminar flow in preparation for TSA. Furthermore, the unrealistic reduction in PJI (35% at this high-volume institution) required to justify laminar flow installation and maintenance was demonstrated. Therefore, despite the theoretical efficacy, the installation of overhead laminar flow systems is likely an unwise use of resources in this cost-conscious era of healthcare.

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FIGURE AND TABLE LEGENDS

Figure 1. Formula for break-even analysis adjusting future cost and savings to net-present-value (NPV). PJI cost=cost of treating PJI; PJI incidence=baseline risk of PJI; Effect=rate of reduction of PJI by laminar flow; Installation=cost of installation; Maintenace=annual cost of maintenance; Longevity=expected years of ventilation (laminar flow) system use; TSA=annual volume of total shoulder arthroplasty.

Figure 2. An example of solving the break-even formula (Figure 1) for a desired variable; in this instance, annual volume of total shoulder arthroplasty.

Figure 3. Per case cost of laminar flow utilization for each annual volume of total shoulder arthroplasty studied.

Figure 4. The number of annual volume of total shoulder arthroplasties required in a single operating room to break-even on the investment of laminar flow for varying rates of reduction of periprosthetic joint infection.

Table 1. Variables included in cost equation with the designated averages, standard deviations for sensitivity analysis, and source of these designations.

Table 2. This table demonstrates the change tested variables based on tested arthroplasty volumes as well as changing optimal installation and maintenance costs.