Each year, approximately 800,000 people suffer a new or recurrent stroke. Stroke is a significant cause of long-term disability, with more than half of stroke patients being discharged from the hospital to inpatient rehabilitation or skilled nursing facilities. Of patients discharged home, 32% utilized home healthcare services. Stroke is also a major cause of mortality, accounting for 1 death every 4 minutes and 1 of every 20 deaths in the US. The probability of death within the first 5 years after a stroke is highest in patients older than 75 years of age.

These data underscore the importance of effective treatment of acute ischemic stroke. In 2015, the publication of multiple trials demonstrated improved rates of functional independence in patients undergoing mechanical thrombectomy compared to those treated medically alone. Despite an incremental cost of $10,840 compared to medical therapy, the improvement in functional outcomes and decreased disability have contributed to the cost-effectiveness of the procedure. In this study the authors describe a physician-led device bundle purchase program implemented for the delivery of stroke care.

OBJECTIVE The mortality rates for stroke are decreasing, yet it remains a leading cause of disability and the principal neurological diagnosis in patients discharged to nursing homes. The societal and economic burdens of stroke are substantial, with the total annual health care costs of stroke expected to reach $240.7 billion by 2030. Mechanical thrombectomy has been shown to improve functional outcomes compared to medical therapy alone. Despite an incremental cost of $10,840 compared to medical therapy, the improvement in functional outcomes and decreased disability have contributed to the cost-effectiveness of the procedure. In this study the authors describe a physician-led device bundle purchase program implemented for the delivery of stroke care.

METHODS The authors retrospectively reviewed the clinical and radiographic data and device-associated charges of 45 consecutive patients in whom a virtual "stroke bundle" model was used to purchase mechanical thrombectomy devices.

RESULTS Use of the stroke bundle to purchase mechanical thrombectomy devices resulted in an average savings per case of $2900.93. Compared to the traditional model of charging for devices à la carte, this represented an average savings of 25.2% per case. The total amount of savings for these initial 45 cases was $130,542.00. Thrombolysis in Cerebral Infarction scale grade 2b or 3 recanalization occurred in 38 patients (84.4%) using these devices.

CONCLUSIONS Purchasing devices through a bundled model resulted in substantial cost savings while maintaining the therapeutic efficacy of the procedure, further pushing the already beneficial long-term cost-benefit curve in favor of thrombectomy.
Achieving good or exceptional quality designations. According to retrospective bonus payments that increase as hospitals incentivizes quality and cost containment by “providing utility and cost of medical devices is one factor familiar of care metrics, and insurance status and coverage), the payment structure, CMS criteria and expectations, quality efforts to optimize the purchase price of devices (thereby increasing the cost savings and reducing the overall cost of stroke care delivery) could be a natural and effective means for physician-led impact. In this paper we describe our experience using a virtual “stroke bundle” to encompass the costs of devices used in performing mechanical thrombectomy. Using a “bundle purchase program,” we have achieved a significant reduction in the device costs of mechanical thrombectomy incurred by hospitals, while maintaining the effectiveness of the procedure. To our knowledge, this is the first description of a physician-led bundle purchase program implemented for the delivery of stroke care.

**Methods**

After receiving IRB approval from the University at Buffalo, we retrospectively analyzed the clinical and radiographic data of 45 consecutive patients undergoing mechanical thrombectomy for acute ischemic stroke at our institution in whom a stroke bundle was used to purchase mechanical thrombectomy devices between December 1, 2018, and February 15, 2019. In the “bundle purchase program,” there is a flat fee for the devices used to perform mechanical thrombectomy. Because the devices may be different depending on the thrombectomy strategy (e.g., stent retriever vs aspiration, radial vs femoral access), we developed several versions of the bundle (Table 1). The devices used in the “bundle purchase program” included the Avigo 0.014-inch microwire (Medtronic), Phenom 0.027-inch or Marksman 0.027-inch microcatheter (Medtronic), React 0.068-inch aspiration catheter (Medtronic), Cello 8-Fr balloon guide catheter (Medtronic), and Solitaire revascularization device (Medtronic).

We evaluated the charges associated with the devices used to perform mechanical thrombectomy. We then compared the device-related costs of the procedure using the previous “à la carte charging” model (e.g., charging for each device individually) to the bundle cost to calculate a percentage of savings for each case.

**Results**

We identified 45 patients who underwent mechanical thrombectomy with devices included in the bundle purchase program. The occlusions were located in the internal carotid artery (ICA; n = 8, 17.8%), M1 segment of the middle cerebral artery (MCA; n = 18, 40%), M2 MCA segment (n = 12, 26.7%), M2 MCA segment (n = 1, 2.2%), basilar artery (n = 4, 8.9%), and the P12 posterior cerebral artery junction (n = 2, 4.4%).

Using the stroke bundle, the average savings per case was $2900.93. Compared to the traditional model of charging for devices à la carte, this represented an average savings of 25.2% per case. The total amount of savings for these initial 45 cases was $130,542.00. In 11 cases, using the stroke bundle resulted in more than 40% savings per case. The devices used in these cases are listed in Table 2. In all but one of these cases, we used more than one of a given component of the bundle. Extra devices (i.e., more than one of a given device) were used in 19 cases (42.2%).

Thrombolysis in Cerebral Infarction (TICI) scale grade 2b or 3 recanalization occurred in 38 patients (64.4%). There were two procedural complications: one patient experienced a minor subarachnoid hemorrhage (SAH) seen on a postprocedure CT scan of the head with no clinical consequence, whereas the other patient experienced a perforation during an attempt to cross a hard, recalcitrant

<table>
<thead>
<tr>
<th>Bundle</th>
<th>Description</th>
<th>Device Components</th>
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<tbody>
<tr>
<td>A</td>
<td>Aspiration</td>
<td>Microwire, microcatheter, aspiration catheter, aspiration system (e.g., pump, tubing)</td>
</tr>
<tr>
<td>B</td>
<td>Balloon-guide + aspiration</td>
<td>Microwire, microcatheter, aspiration catheter, aspiration system (e.g., pump, tubing), balloon-guide catheter</td>
</tr>
<tr>
<td>C</td>
<td>Stent retriever</td>
<td>Microwire, microcatheter, stent retriever</td>
</tr>
<tr>
<td>D</td>
<td>Stent retriever + aspiration</td>
<td>Microwire, microcatheter, aspiration catheter, aspiration system (e.g., pump, tubing), stent retriever</td>
</tr>
<tr>
<td>E</td>
<td>Stent retriever + aspiration + balloon-guide</td>
<td>Microwire, microcatheter, aspiration catheter, aspiration system (e.g., pump, tubing), balloon-guide catheter, stent retriever</td>
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occlusion (during the fourth pass). This resulted in a type 1 parenchymal hemorrhage\textsuperscript{a} that was managed conservatively.

Discussion

In 2015, 5 prospective randomized trials that simultaneously demonstrated class I evidence emerged in support of the use of mechanical thrombectomy for the treatment of acute ischemic stroke in anterior circulation large-vessel occlusion.\textsuperscript{3,6,10,11,19} These trials demonstrated statistically significant improvements in functional outcome among patients undergoing mechanical thrombectomy (primarily with stent retrievers) compared to those receiving medical therapy (intravenous tissue plasminogen activator) alone.

As with any new procedure utilizing new devices, mechanical thrombectomy can be costly. Kim et al. found that mechanical thrombectomy cost $10,840 more than medical therapy alone.\textsuperscript{12} When one considers that stroke affects approximately 800,000 individuals per year and approximately 33% may be eligible for mechanical thrombectomy,\textsuperscript{21} the annual incremental cost becomes exorbitant. Despite these costs, mechanical thrombectomy has been shown in multiple recent analyses to be cost effective, primarily because of resultant reductions and related costs in long-term disability and need for rehabilitation at long-term care facilities.\textsuperscript{2,9,12,20} In the study by Kim et al., mechanical thrombectomy was found to have an incremental cost-effectiveness ratio of $16,001 per quality-adjusted life year and to be cost effective, provided that procedural and hospital costs remained under $47,600.\textsuperscript{12}

With the ever-mounting rise in healthcare costs, reduction of healthcare expenditures and the concept of cost effectiveness are of increasing importance. To address these issues, CMS implemented bundled payments for reimbursement of certain medical conditions and procedures. This reimbursement model has been well established for hip and knee joint replacement. This program incentivizes quality and cost containment by “providing retrospective bonus payments that increase as hospitals exceed their quality and cost benchmarks.”\textsuperscript{16} Early data from this program found that nearly 50% of participating hospitals received bonus payments, with 92% of those achieving good or exceptional quality designations.\textsuperscript{16}

DRG episode-based payment bundles are utilized in ischemic stroke to account for the acute hospitalization associated with the disease. However, the cost of stroke also includes not only the hospitalization but also the ambulance and/or helicopter transport, emergency room visit, inpatient rehabilitation, and outpatient expenses. Dobbs found inpatient rehabilitation to be the greatest cost encountered during the treatment of a patient with ischemic stroke.\textsuperscript{7} As mentioned, mechanical thrombectomy has significantly decreased the degree of disability, thereby decreasing the time spent in inpatient rehabilitation, albeit at a cost. Although the costs associated with inpatient rehabilitation are complex and less tangible, those associated with mechanical thrombectomy represent an avenue to introduce additional savings into the treatment of acute ischemic stroke.

Drawing inspiration from an unlikely and ironic source, the fast food industry, we implemented a bundle purchase model for mechanical thrombectomy devices. Not unlike the industry’s “value meal” that contains several items at a lower cost than the sum of their individual costs, we created stroke bundles in which the cost is for the entire bundle at a rate discounted from the sum of the individual components. Just as there are multiple value meal options at fast food restaurants, there are multiple versions of the stroke bundle (Table 1), each with a variety of devices suited for different scenarios.

In implementing this concept, it is important to recognize that the stroke bundle is not a physical entity. Rather, similar to the retrospective bonus payments provided by CMS for high quality, the stroke bundle is “virtual.” The devices are initially charged in the usual fashion, and a rebate is issued after retroactively adjusting for the bundled cost. When a given component of a bundle is not used, the price of that device is subtracted from the rebate and the amount is adjusted (Fig. 1).

\begin{table}[h]
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\small
\caption{List of devices used in which the “purchase bundle program” resulted in more than 40% savings per case compared to the “à la carte” purchase model}
\begin{tabular}{|c|c|c|c|}
\hline
Consecutive Case No. & Devices Used & Cost of Extra Devices & \% Savings per Case* \\
\hline
6 & Microwire, microcatheter, aspiration system, stent retriever (x2) & $6000 & 56.7 \\
11 & Microwire, microcatheter (x2), aspiration catheter, aspiration system, stent retriever (x2) & $7200 & 48.1 \\
15 & Microwire (x3), microcatheter, aspiration system, stent retriever (x2) & $6948 & 53.1 \\
17 & Microwire, microcatheter, aspiration system, stent retriever (x2) & $6000 & 50.0 \\
22 & Microwire, microcatheter, aspiration catheter, aspiration system, stent retriever (x2) & $6000 & 48.1 \\
27 & Microwire (x2), microcatheter, aspiration catheter, aspiration system, stent retriever & $1200 & 44.4 \\
31 & Microwire (x2), microcatheter, aspiration catheter, aspiration system, stent retriever (x2) & $7572 & 51.6 \\
32 & Microwire, microcatheter, aspiration catheter, aspiration system & $0 & 47.2 \\
35 & Microwire, microcatheter, aspiration catheter, aspiration system, stent retriever (x2) & $6000 & 48.1 \\
38 & Microwire, microcatheter, aspiration catheter, aspiration system, stent retriever (x2) & $6000 & 48.5 \\
45 & Microcatheter, aspiration catheter, aspiration system, stent retriever (x2) & $6000 & 46.6 \\
\hline
\end{tabular}
\* Percentage savings per case = (bundled cost/à la carte cost) × 100.
Because this is a “virtual” and not a physical bundle (i.e., all the devices are not purchased together in a single package), the physician is free to use appropriate devices from multiple manufacturers and is not influenced or forced to purchase any devices that he or she does not want to use. For example, should we prefer to use a guide catheter that is outside the bundle, we are not prohibited from the savings afforded by the bundle program. Rather, we use whichever guide catheter we feel is best, and the remaining devices (e.g., aspiration catheter, microwire, microcatheter, and stent retriever) are bundled (bundle D in Table 1). Similarly, in certain situations (e.g., stroke treatment from a radial approach in which an aspiration catheter that is compatible with a 6-Fr guide catheter is required), we have used an aspiration catheter that is not within the bundle and the remaining devices (e.g., microwire, microcatheter, and stent retriever) are bundled (bundle C in Table 1). In this way, use of the “virtual” bundle does not prohibit physician choice. One example of this is a case in which the devices consisted of the aspiration catheter, the tubing and canister, 2 microcatheters, and 1 stent retriever; the total cost of these devices if purchased individually would have been $11,398, but the bundled price was $8400, resulting in a savings of $2998.

The savings afforded by the stroke bundle are even greater if a physician neurointerventionist requires additional devices to complete the procedure. An example may be a neurointerventionist who considers opening a new retrievable stent because the device chosen initially may not be sized appropriately or is performing suboptimally. Another example may be a physician neurointerventionist questioning whether he or she should open a new microwire to replace a bent or fatigued wire. The ability to choose another device (“all you can eat” in the fast food model) without incurring additional costs removes financial constraints and utilization pressures, allowing the use of multiple devices as needed to provide the best patient care. One example of this is a case in which we encountered a calcified, recalcitrant thrombus requiring 5 passes. In this case, we used 3 microwires, 1 microcatheter, the tubing and canister, and 2 stent retrievers; the cost of these devices if purchased individually would have been $15,146, but the bundled price was $7100, resulting in a savings of $8046.

Utilization of the stroke bundle has not had any adverse clinical consequences. Our rate of adequate recanalization (TICI grade 2b or 3) was 84.4% and compares favorably to that reported in the literature. In patients undergoing mechanical thrombectomy, TICI grade 2b or 3 recanalization was achieved in 58.7% in the MR CLEAN trial, in 86% in the EXTEND-IA trial, and in 88% in the SWIFT PRIME trial. We experienced no device failures. In 19 cases (42.2%), we utilized more than one of a particular device. The average savings per case in these instances was 25.2%; i.e., the use of additional devices did not negatively affect the savings per case. Over the initial 2.5 months of adoption of this program at our institution, we have saved more than $125,000. Extrapolated over the year, this would result in an annual savings exceeding $600,000.

We experienced two procedure-related complications. Although one of them is not an uncommon occurrence after mechanical thrombectomy (i.e., minor SAH in the revascularized territory), the other was a perforation resulting in a type 1 parenchymal hemorrhage. This patient had a recalcitrant occlusion of the left superior MCA trunk. Three passes had been performed with a retrievable stent. Because of the patient’s neurological deficit (NIH Stroke Scale score of 15), we prepared to perform angioplasty. We experienced significant difficulty crossing the clot, and a contrast injection performed after crossing demonstrated extravasation. We hypothesize that a wire perforation occurred during our attempt to cross this recalcitrant lesion. It should be noted that we had chosen to use a different microwire (one outside the bundle) due to the more distal location and firm nature of the occlusion.

The guide catheter that was included in the bundle was not used in any of the cases reported here. Our preference is to use navigable guide catheters that can be advanced into the distal cervical or proximal intracranial ICA rather than into the carotid artery.
than balloon-guide catheters, which are the guide catheters that are included in the bundle. It is our feeling that other guide catheters, outside of the bundle, are superior to the one within it. Nevertheless, the bundle afforded savings. Furthermore, this highlights that the stroke bundle does not restrict the physician neurointerventionist in his or her choice of device.

Limitations

Our study has several limitations. The data represent a retrospective review of thrombectomies performed at our institute over a short period of time. Therefore, we are unable to analyze the long-term impact of the bundle purchase program; any inferences about the long-term effectiveness of this program are based on projections from our initial experience. Additionally, at our institute, we perform approximately 200 thrombectomies annually. This is indicative of a high-volume thrombectomy center, which may have afforded us a relatively unique ability to negotiate bundle pricing.

The cost of health care delivery is affected by innumerable factors, with entire fields and advanced degrees (e.g., health care administration, Master of Business Administration) devoted to their study. Therefore, it is possible that the savings afforded by the bundle purchase program described here may be negated by other increases in cost. An analysis of the interplay between the multitude of factors that affect the cost of health care delivery is outside the scope of this paper. Rather, here we aimed to propose a relatively simple means by which physicians can make a meaningful difference in the overall cost of stroke care delivery. The devices used in mechanical thrombectomy are familiar to all who perform the procedure, making this a tangible and seemingly natural avenue through which any and every neurointerventionist can easily be involved. Furthermore, as a physician-led effort, quality delivery of care (predicated on the necessary devices) can be preserved and the use of suboptimal devices suggested by nonpractitioners in the interest of cost-reduction can be avoided.

Conclusions

Although the concept of the “extra value meal” started with a single McDonald’s franchise in the early 1990s, it is now a staple across the fast food industry. Similarly, while bundled reimbursement was applied initially to only a few select procedures, it is now being expanded. As our experience with bundled device purchasing grows and the resultant cost savings are realized, we anticipate that widespread implementation of such a program will improve the risk-sharing balance so that device companies share a greater amount of the cost of acute stroke care. On a final note, it is imperative that clinicians share the responsibility to control health care expenditures, while continuing to raise the quality of care for all patients.

Key Points

1. Stroke is a leading cause of adult morbidity and mortality.

2. The incremental cost of mechanical thrombectomy is $10,840 compared to medical therapy alone. However, its improvement in functional outcome and avoidance of disability makes it a cost-effective procedure.

3. For mechanical thrombectomy, purchasing devices through a virtual bundled model resulted in a significant hospital cost savings compared to the traditional model of à la carte device purchasing.

4. Adoption of bundled purchasing may improve the risk-sharing balance so that device companies share an increased portion of the cost of acute stroke care.

5. To our knowledge, this is the first bundled purchase program applied to mechanical thrombectomy.

References


Disclosures

Dr. Davies reports receiving a research grant (no. KL2TR001413) from the National Center for Advancing Translational Sciences of the NIH awarded to the University at Buffalo; being a consultant to Medtronic; receiving honoraria from Neurotrauma Science, LLC; and having shareholder/ownership interests in RIST Neurovascular and Cerebrotech. Dr. Levy reports shareholder/ownership interests in NeXtGen Biologics, RAPID Medical, Clarlet Medical, Cognition Medical, Imperative Care (formerly the Stroke Project), Rebound Therapeutics, StimMed, and Three Rivers Medical; being on national principal investigator/steering committees for Medtronic (merged with Covidien Neurovascular) SWIFT Prime and SWIFT Direct Trials; receiving honoraria from Medtronic (training and lectures); being a consultant for Clarlet Medical, GLG Consulting, Guidepoint Global, Imperative Care, Medtronic, Rebound, and StimMed; serving on the Advisory Board for Stryker (AIS Clinical Advisory Board), NeXtGen Biologics, MEDX, Cognition Medical, and Endostream Medical; being a site principal investigator for the CONFIDENCE study (MicroVention) and STRATIS Study—Sub I (Medtronic); and rendering medical legal opinions as an expert witness. Dr. Siddiqui reports financial interest/investor/stock options/ownership in Amnis Therapeutics, Apama Medical, Blink TBI Inc., Buffalo Technology Partners Inc., Cardinal Consultants LLC, Cerebrotech Medical Systems Inc., Cognition Medical, Endostream Medical Ltd., Imperative Care, International Medical Distribution Partners, Neurovascular Diagnostics Inc., Q’Apel Medical Inc., Rebound Therapeutics Corp., Rist Neurovascular Inc., Serenity Medical Inc., Silk Road Medical, StimMed, Synchron, Three Rivers Medical Inc., and Viseon Spine Inc; serving as a consultant and/or on the advisory board of Amnis Therapeutics, Boston Scientific, Canon Medical Systems USA Inc., Cerebrotech Medical Systems Inc., Cereneovus, Corindus Inc., Endostream Medical Ltd., Guidepoint Global Consulting, Imperative Care, Integra LifeSciences Corp., Medtronic, MicroVention, Northwest University–DSMB Chair for HEAT Trial, Penumbra, Q’Apel Medical Inc., Rapid Medical, Rebound Therapeutics Corp., Serenity Medical Inc., Silk Road Medical, StimMed, Stryker, Three Rivers Medical Inc., VaSol, and W.L. Gore & Associates; and being a principal investigator and/or steering comment on the following trials: Cerenovus LARGE and ARISE II, Medtronic SWIFT PRIME and SWIFT DIRECT, MicroVention FRED trial & CONFIDENCE study, MUSC POSITIVE, Penumbra 3D Separator, COMPASS, and INVEST. Dr. Snyder reports consulting and teaching for Canon Medical Systems Corporation, Penumbra Inc., Medtronic, and Jacobs Institute; and being a co-founder of Neurovascular Diagnostics, Inc.

Author Contributions

Conception and design: Levy, Munich. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: Munich. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors.

Correspondence

Elad I. Levy: University at Buffalo, NY. elevy@ubns.com.