OPEN

The Impact of Hydrocephalus Shunt Devices on Quality of Life

Kerry-Ann S. Mitchell, MD, PhD, Ian Zelko, BS,† Tamir Shay, MD,‡§ Sydney Horen, BA,‡ Ally Williams,|| Mark Luciano, MD, PhD,¶ Judy Huang, MD,¶ Henry Brem, MD,¶ and Chad R. Gordon, DO, FACS||¶*

Background: Despite advances in hydrocephalus shunt technology and improvement in hydrocephalus management, many patients have chronic disability and require multiple surgeries throughout their lifetime. There is limited data from patients' perspective regarding the impact of shunt devices on quality-of-life.

Methods: A cross-sectional survey was developed to evaluate the impact of shunt devices on patient quality-of-life. The survey was distributed via social media platforms of the Hydrocephalus Association, and patients self-selected to anonymously complete the online questionnaire. A literature review was performed to contextualize the findings from the survey.

Results: A total of 562 survey responses were obtained from a network encompassing 35,000 members. The mean age was 30 years old (0.5–87), and 65% identified as female. Eighty one percent underwent at least 1 shunt revision surgery, with a reported average of 10 shunt revision surgeries per patient (1–200 surgeries). Occlusion, shunt migration and infection were the leading causes for revision at 60%, 47%, and 35%, respectively. In addition, 72% of patients reported pain and discomfort from the device, and 68% expressed avoidance of certain activities due to "fear of bumping shunt." Despite numerous articles discussing shunt technology, a review of the literature indicated a paucity of studies specifically evaluating the burden of shunt devices from a patient/caregiver perspective.

Conclusions: The findings from this study suggest long-term physical and psychosocial burden associated with shunt devices. Importantly, this study highlights the need for concerted efforts to develop validated tools to study patient reported outcomes as it relates to neurocranial implanted devices.

Key Words: Burden, devices, hydrocephalus, neurotechnology, quality of life, shunt, ventriculoperitoneal

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Hydrocephalus is a major cause of morbidity worldwide, affecting over 1 million people in the United States with an estimated global prevalence of 85/100,000.[1] Given that there is currently no effective medical therapy, management is primarily by means of a subcutaneously implanted shunt placed in the subgaleal plane of the scalp for cerebrospinal fluid diversion.[2] Regardless of the type of valve utilized, shunts have a higher failure rate than most implanted medical devices on today's market and are estimated to have just 50% efficacy in the first 2 years following placement.[3–5] Furthermore, the literature is abundant with details of shunt complications, including infection, migration, obstruction, mechanical failure, under- drainage, and over-drainage.[6] This leads to multiple patient readmissions with a high financial burden and revision surgeries affecting quality of life (QoL).[7]

Studies show that even shortly after shunt placement, patients can develop headaches, pain, fatigue, and are at risk for early shunt malfunction.[8] Over time, this risk for complications may persist. As such, patients or caretakers must remain alert to symptoms of shunt malfunction and report them to their physician in a timely manner to prevent further deterioration. If and when symptoms arise, this may lead to hospitalizations and necessary, but undesired, procedures. In fact, a study by Paulsen et al[9] demonstrated that patients who have endured multiple shunt revisions express a decreased self-perception of health. Similarly, Beez et al[10] demonstrated that even patients who may not endorse a reduced QoL per se, do modify their lifestyles to adapt to the presence of a shunt. Despite an understanding of the considerable burden of hydrocephalus disease, the life-saving clinical impact of shunts, and the clinical and economic morbidity related to shunt-related complications, there remains a paucity of data regarding how the devices themselves impact QoL.

When investigating the overall burden of a disease, clinical manifestations and economic costs tend to capture the greatest interest of clinicians and payers, respectively, and therefore garner the focus of

From the *Department of Plastic and Reconstructive Surgery, The Ohio State University Wexner Medical Center, Columbus, OH; †Chicago College of Osteopathic Medicine, Midwestern University, Chicago, IL; ‡Department of Plastic Surgery and Burns, Rabin Medical Center, Petah Tikva; §Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel; ||Section of Neuroplastic and Reconstructive Surgery, Department of Plastic and Reconstructive Surgery; and ¶Department of Neurosurgery, Johns Hopkins University School of Medicine, Baltimore, MD.

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Address correspondence and reprint requests to Kerry-Ann S. Mitchell, MD, PhD, Department of Plastic and Reconstructive Surgery, The Ohio State University Wexner Medical Center, 915 Olentangy River Road, Suite 2140, Columbus, OH 43212; E-mail: kerry-ann.mitchell@osumc.edu

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most research efforts. However, once the clinical burden of the disease is relieved by the treatment modality, the humanistic burden of either the treatment devices or the disease itself typically becomes of great concern to patients and their caregivers. The humanistic burden considers the impact of an illness on a patient's health related QoL, activities of daily living, caregiver QoL, and patient satisfaction. Although several studies have previously been published on the clinical burden of shunted hydrocephalus, the humanistic burden of the shunts themselves have not being examined in these studies.[11–13] This understanding is essential in order to increase awareness, formulate strategies to improve the devices, and enable proportionate resource allocation to investigate and optimize shunt design and functionality. With this in mind, the present study aims to qualitatively assess the humanistic burden of shunts through a cross sectional survey and a review of the relevant literature.

MATERIALS AND METHODS

Cross-Sectional Survey

Given that there is currently no validated survey available for examining neuroplastic surgery in general and/or shunt-related burden specifically, based on literature review and expert opinion, we developed a 11-item questionnaire exploring subjective burden of shunts in terms of number of revision surgeries, impact on everyday life and impact on special activities (Supplementary Digital Content, 1, http://links.lww.com/SCS/C528). We enlisted aid from the Hydrocephalus Association, a national patient advocacy organization, for survey distribution to their existing network of hydrocephalus patients, patient representatives, and/or caregivers. The cross-sectional survey was distributed electronically across their social media platforms (October 2018), and all active patient members and/or representatives were invited to participate over a 1-month time period.

At the time of the survey distribution, potentially 35,000 people could have responded via the social media sources utilized based on follower data. However, due to the metrics available from these social media sources, it was not possible to determine whether that 35,000 represents unique patients, or the number of individuals who actually saw and/or reviewed the survey. The tabulated responses from all survey participants were analyzed and included in this report.

Literature Review

In order to contextualize the findings from our study with regards to similar studies, a comprehensive search of the PUBMED database was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[14] Each search was conducted using controlled vocabulary and key words, and was limited to articles published in English and involving human subjects. Search term combinations included the following: "quality of life," "burden," "health-related quality of life," and "patient-reported outcome." These terms were combined with general terms covering hydrocephalus and hydrocephalus shunt devices, spanning the years 1951 to 2020.

After removing duplicate articles according to PMID, titles and abstracts of the remaining articles were reviewed by an initial research group. The target population consisted of patients from any age group with the following inclusion criteria:

(1) diagnosis of hydrocephalus, and
(2) history of placement of shunts.

The inclusion criteria were further limited to articles that specifically studied the impact of shunts on QoL, or the burden of shunts. Patients with placement of lumboperitoneal (LP) shunts were excluded given that the proximal location of these devices is notably different and not comparable to that of ventricular-based shunts. After articles that did not meet the inclusion criteria were screened out, the full texts of the remaining articles were reviewed in detail. Information was recorded for study design, setting, patient characteristics, outcome measures, key results, and conclusions. Given the descriptive nature of this systematic review, the extracted data were narratively synthesized.

RESULTS

Cross-Sectional Survey

A total of 562 patients completed the survey questionnaire for inclusion into this study. The demographic characteristics of all participants are summarized in Supplementary Digital Content, Table 1, http://links.lww.com/SCS/C525. The mean age was 30 years (from 0.5–87 years), with a predominance of female respondents (n = 363, 65%). Seventy-eight percent (n = 441) of respondents were adults (defined as >18 years old), whereas the remaining 22% (n = 115) were less than 18 years old.

Of the respondents, 83% (n = 464) had their first shunt surgery performed before 21 years old, with the majority having their first shunt surgery between the ages of 2 and 12 years old (65%, n = 364) (Fig. 1). Almost half the patients (n = 245, 44%) reported their first shunt procedure was performed over 20 years before the time this survey was administered (Supplementary Digital Content, Table 2, http://links.lww.com/SCS/C526). Forty-six percent indicated their shunt had been inserted on the posterior aspect of the head, 42% indicated an entry point on the anterior aspect, and 12% reported both anterior and posterior insertion points.

Eighty-one percent (n = 455) of respondents indicated that they had undergone at least 1 shunt revision procedure. On average, each patient had undergone 10 revisions over the course of their lifetime, with a range of 1 to 200 surgeries. Most patients (n = 266, 58%) underwent between 1 and 5 revision surgeries, whereas 9% (n = 39) indicated they had undergone over 25 shunts revision surgeries. The distribution of the number of revision surgeries reported is demonstrated in Figure 2.

With regards to reason for needing shunt revision surgery, respondents were provided the option to select from a list of one or more common indications (Fig. 3). Shunt-related issues were the most common indications reported for surgical revision, with 60% (n = 337) of respondents selecting "shunt occlusion," and 47% (n = 264) selecting "shunt migration" as reason for shunt revision.

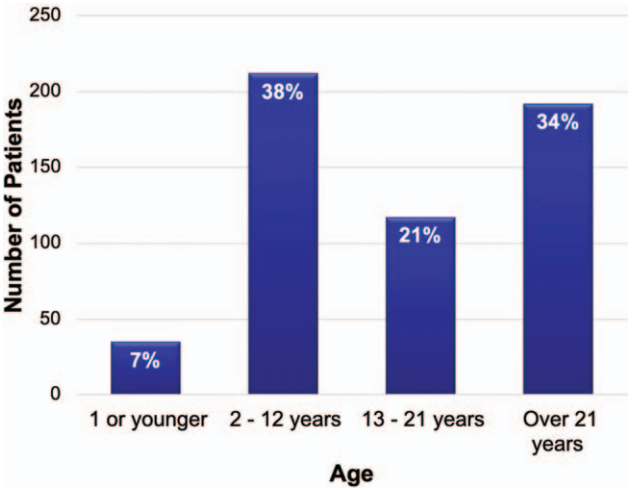

FIGURE 1. Age of first shunt device placement per survey respondent.

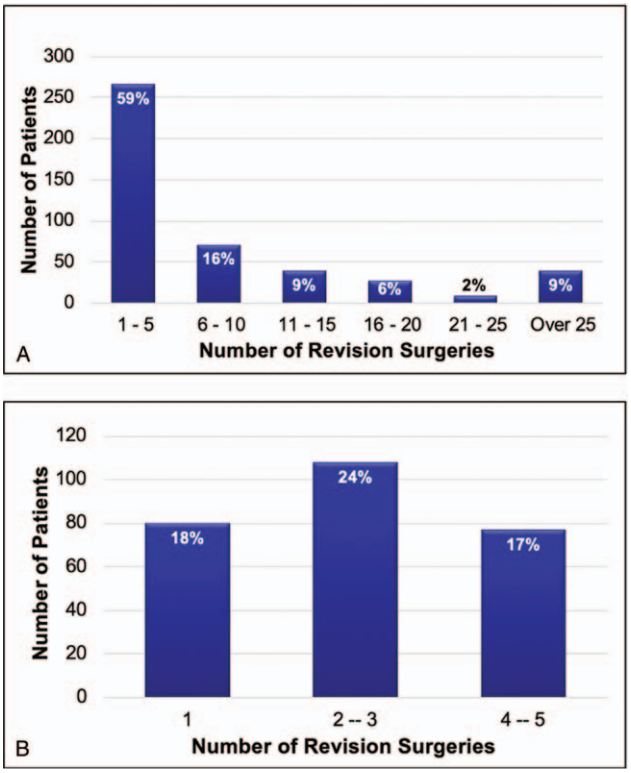

FIGURE 2. Number of revision surgeries per survey respondent. Four hundred and fifty-five patients reported having at least 1 revision surgery, in addition to their original (ie, index) operation for hydrocephalus shunt placement. (A) Breakdown of the number of revision surgeries per patient survey response. Of note, 59% percent of respondents had between 1 and 5 revision surgeries. (B) Further breakdown of the 1 to 5 revision surgery categories.

Soft tissue-related indications included "infection" (35%, n = 197), "wound breakdown" (7%, n = 39), and "scalp pain/discomfort" (4%, n = 22).

Interestingly, 72% (n = 398) of patients reported having experienced pain at the shunt site. Sixty-seven percent noted they feared bumping the shunt, with 42% (n = 235) noting they avoided resting their head on the side with the shunt, and 43% (n = 243) avoided sports, exercise, or outdoor activities (Supplementary Digital Content, Table 3, http://links.lww.com/SCS/C527, Fig. 4). A smaller percentage of patients noted that having the shunt led them to avoid

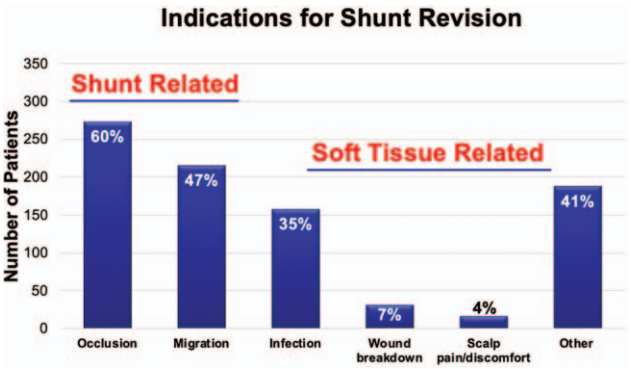

FIGURE 3. Reasons for hydrocephalus shunt revision reported by each survey respondent. Respondents were given the option to select one or more reasons for shunt failure, given that they may have had multiple shunt failures requiring revision. A total of 455 surveyed patients reported having at least 1 shunt failure requiring surgical revision (81%, out of 562 surveys).

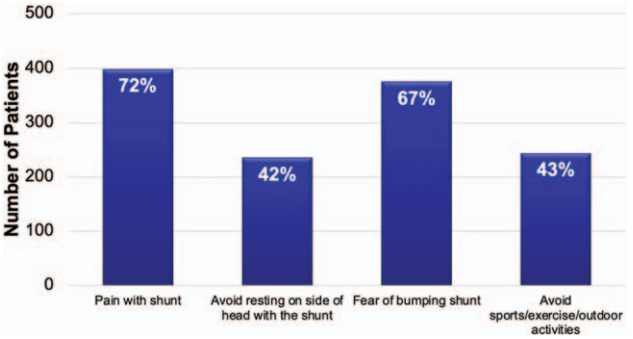

FIGURE 4. Patient report on routine activities avoided secondary to having a shunt.

theme park rides, wearing headwear or glasses, or impacted hair grooming (Supplementary Digital Content, Table 3, http://links.lww.com/SCS/C527).

Literature Review

After screening and removing all duplicate articles, a total of 129 articles relating to shunt and QoL were identified and analyzed. Of these, 70 evaluated the impact of hydrocephalus on the QoL, without specifically evaluating the shunt device itself. Thirty-nine peripherally discussed hydrocephalus and/or issues related to QoL, and 9 studied LP shunts. Three were editorials/commentaries that did not evaluate specific data. An additional 7 were not in English, but a review of these abstracts demonstrated that these studies otherwise did not meet inclusion criteria. As such, this exhaustive review yielded only 1 study examining the impact of shunts on QoL, and the details of that study are narratively summarized herein.

In 2018, Beez et al[10] identified 15 patients between the ages of 3 to 21 years old (mean 12 years), and contacted their families to complete a set of 2 standardized questionnaires used to assess headache and QoL. They found that 87% of respondents reported satisfaction with the shunt and improvement in hydrocephalus symptoms, and the majority (67%) only rarely experienced headaches (less than once per month). However, 53% of the respondents noted that they take precautions before special activities such as traveling, and 33% described subjective limitations with regard to sports (gymnastics, water sports, cycling, football) and/or precautions to avoid bumping or touching the valve.

Although the Hydrocephalus Outcome Questionnaire is a well-established means of measuring QoL in patients with hydrocephalus and there were a number of studies utilizing this tool, this questionnaire does not assess patients' perspectives on the shunt itself.[15–17] Similarly, the Short Form Health Survey (SF-36) self-assessment tool was also used in a number of studies to evaluate self-reported health related QoL, however this survey does not ask specific questions related to shunts.[9,18,19]

DISCUSSION

Ventriculoperitoneal shunting is the most commonly used surgical treatment for managing hydrocephalus, with over 30,000 procedures performed annually in the United States.[20] Despite significant advances in shunt valve technology since inception, innovation in surgical technique and device placement has remained modest, with the greatest impact being from use of intraoperative navigation and regulation of cerebrospinal fluid drainage. Though vital and life-supporting, hydrocephalus shunts experience a higher failure rate than the majority of medical devices used today and are associated with significant morbidity.[4] Frequent complications, such as infection and shunt malfunction, lead to a significant number of revision

surgeries, hospital readmissions, and over 50 million dollars of economic expenditure per year.[21] Newer shunt valves that may ultimately prove more effective in managing hydrocephalus tend to have an even larger design profile, thus increasing their odds for adverse impact in terms of visibility, pressure on the overlying scalp, and being more prone to soft tissue related complications.[5] Although there is considerable amount of data on complication and shunt failure rates, the humanistic burden of the shunts themselves is not well studied.[8,22,23] A possible reason for this may be that clinicians and researchers may be more focused on addressing the more pressing life-threatening effects of hydrocephalus itself (ie, brain function), rather than what may be considered psychosocial or lifestyle burden. Thus, the aim of this study was to utilize a cross-sectional survey to determine whether shunts adversely impact patient QoL.

The results of this study indicate that a high proportion of respondents are afraid of bumping or dislodging their shunt system, leading to avoidance of routine activities. These activities included, but were not limited to, sleeping/resting on the side of the head with the shunt, exercising, playing sports, engaging in outdoor activities or even wearing headgear or glasses. Generalized fear, anxiety, or paranoia was also reported both in this survey and by Beez et al,[10] with patients reporting hypervigilance of surroundings and shunt reservoir site. From these reports, it is apparent that shunt systems, and the cognizance thereof, interfere with patient QoL. Consistent with the literature, shunt infection was the most significant complication after mechanical failure, with previous studies indicating an incidence ranging between 1% and 35% (mean average = 5%–15%), depending on patient age and comorbidities.[24,25] Shunt infection occurs due to the unintentional introduction of microorganisms to system components both intra- and post-operatively, resulting in the formation of a pathogenic biofilm. Immediate postoperative infection is generally due to components of the shunt system coming in contact with skin flora before implantation (or break in surgical sterility), whereas a delayed infection may be associated with bowel perforation or peritonitis by the abdominal catheter, or as result of incisional surgical site infection. Wound complications (ie, breakdown, dehiscence, scalp extrusion) and scalp pain can be mostly attributed to the nonanatomical, subgaleal placement of the ventricular catheter creating tension on the scalp above, strain on the incision closure and and/or pressure on the overlying scalp which may result in further complication (ie, infection, extrusion, incision dehiscence, tissue necrosis, etc).[5,26,27] Indeed, in our experience we have noted visible and palpable associated deformities and pressure on the overlying scalp from the high-profile shunts, which secondarily causes scalp pain, ischemia, and eventually breakdown of the skin protecting the shunt.

Over 40% of patients reported "other" rationales for shunt revision, which may relate to any variety of complications with regard to over- or under-drainage, cerebrovascular complication, multiloculated hydrocephalus, shunt failure to relieve pressure/symptoms, and more. The high rate of unidentified revision rationale may also be explained by self-reporting measures being prone to confusion in presented terminology or treatment course, resulting in incorrectly categorized surgical indication. Nevertheless, available historical literature clearly echoes the survey results with regards to shunt revision surgeries.[7,22,28] These findings further support the notion that expanded research efforts in this area are undoubtedly warranted.

There are several limitations to this study that warrant discussion. Firstly, a nonvalidated survey instrument was utilized, given the lack of a currently available validated instrument.

Although the SF-36 and the Hydrocephalus Outcome Questionnaire surveys have both been utilized in studying QoL in patients with hydrocephalus, these are generic instruments that do not specifically address the impact of the shunts.[9,17–19,29,30] Thus, this evaluation necessitated the development of a survey questionnaire. This preliminary data supports the need for rigorous, validated patient reported outcome (PRO) instruments to perform prospective studies comparing patients with hydrocephalus shunts versus those who were managed with endoscopic treatment. Secondly, although the results of the survey illustrate patient perspectives regarding the shunt, the results may not be totally representative of the entire hydrocephalus patient community. Nonrandom patient sampling is prone to self-selection bias, (ie, patients most affected may be more likely to be activists and members of patient advocacy groups) and more likely to participate in surveys such as this one. Even though there were greater than 500 respondents participating, this represents a relatively small proportion compared to the entire distribution network, therefore prone to this type of bias as well. Thirdly, demographic results indicate potential age and gender biases, displaying female predominance (65%) and young average participant age (mean = 30 years). Though not inconsistent with literature reports, it is possible for self-selection bias and inflating complication rates or overall psychosocial burden to occur when there is higher respondence from patients with poorer outcomes. Fourthly, this study focuses on adult patients with hydrocephalus. Future studies need to be conducted to evaluate the burden in pediatric populations. Notably, pediatric shunts are typically low-profile, as opposed to the high-profile, programmable shunts often used in adults. Therefore, the 2 populations may not be suitable for straightforward comparison. Finally, this questionnaire focused on possible issues with the proximal catheter of the shunt, excluding potential issues with the distal catheter such as abdominal pain in patients with ventriculoperitoneal shunts. This may be a consideration for future studies with an expanded scope.

Anonymous surveying also presents limitations in accuracy due to questionnaire misinterpretation, misinformation, or misunderstanding about treatment course otherwise circumvented by clinician reports. In an effort to mitigate some of these limitations, a literature review was conducted such that the data could be evaluated in the context of current reports. However, there was a notable paucity of literature related to QoL and humanistic burden of shunt systems, making verification of survey results infeasible. Despite these shortcomings, this study is a small step in the right direction and validates the premise that further research is critically needed for developing/content validating PRO measures to better evaluate the physiological and humanistic burdens associated with shunts. In addition, the new subspecialty known as neuroplastic surgery is committed to investigating PROs for all subsets of neurosurgical patients undergoing device implantation and cranial implant reconstruction.[31]

In comparison, other surgical specialties have begun to objectively analyze the impact of various treatment devices on patient QoL, through validated PRO instruments. For example, the BREAST-Q is a widely utilized instrument in breast surgery, and includes segments evaluating PRO after breast implant (ie, medical device) placement.[32] Increasing realization of the importance of patient-reported outcomes is leading to novel technological approaches for managing diabetes, and diabetes care delivery becoming more patient-centered.[33] Our literature review demonstrates that valid, reliable, and responsive instruments to measure QoL outcomes in neurosurgical devices are lacking. Given the often-lifelong dependence and life-changing impact of shunts, rigorous development and validation of device- specific scales may assist in improving patient outcomes.

In parallel, advances in the burgeoning field of neuroplastic surgery have begun to display the importance of minimizing pressure on the scalp overlying the shunt valve, immobilizing shunt system components to combat migration, and using distant incisions with tension-free multilayer scalp closures.[34] As such, scalp-related complications may be mitigated using valve-agnostic cranioplasty implants for inset within the bone space and antibiotic-impregnated catheter systems.[5,35] Prevention of wound dehiscence and extrusion

in patients with friable/highly-scarred scalps is readily attained through various scalp reconstruction techniques.

Alongside antibiotic-impregnated catheters, it may be possible to reduce shunt infections by reducing scalp breakdown near shunt hardware, which can be accomplished by placing incisions away from the shunt and using local scalp flaps for exposure, as opposed to using an incision directly over the shunt. In addition, by eliminating the capacity for the shunt valve to be "bumped" via reduction of the hardware prominence, the anxiety or discomfort associated with receiving a haircut, wearing a hat, or sleeping on the side of the head housing the shunt may all be ameliorated. Notably, neuroplastic surgery techniques and devices as described here, in addition to educational resources and support systems provided by patient-advocacy groups, provide the potential to improve the humanistic burden associated with shunt systems. Given their relative novelty, further research evaluating the efficacy of ancillary shunts and neuroplastic cranial implants in improving patient QoL, both physiologically and psychosocially, should be pursued.

Although shunts are both life-enhancing and life-saving treatments, the device itself may be associated with physiological and psychosocial burden from a patient perspective. Although surgical treatment options remain limited, modern advances in improved shunt systems should consider mitigation efforts against shunt-related complications. Ultimately, this report identifies need for large scale, comprehensive studies evaluating the burden of shunts on patient QoL with validated survey instruments.

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