Development of a Wearable Intracranial Pressure Monitoring Device

Background Reading/Paper Critical Review

Members: Ese Bowry, Marissa Hsu
Mentors: Joshua Liu, Dr. Chad Gordon, Dr. Mehran Armand

Project Summary

This project is working on the creation of a wireless, wearable intracranial pressure (ICP) monitoring device for monitoring of pressure inside the skull. This device will aid physicians to continuously analyze a connected patient's intracranial pressure levels. Since there is no prior work on this project done in our mentor's lab, this project is a proof-of-concept based project where our central goals are comprised of:

- Prototyping a wearable monitoring device that can be embedded in a cranial implant for measuring a patient's intracranial pressure
- Transferring pressure sensor data to a remote PC/smartphone via Bluetooth
- Live-tracking and feedback analysis in app

Widely used ICP monitoring methods are characterized by the placement of a catheter into the skull that monitors the patient's intracranial pressure after severe head trauma. Usually this type of monitoring is done at the hospital or clinic and must be overseen by trained professionals. Modern ICP devices have worked to create a more compact design consisting of an implantable sensor and connected monitor that can aid in long-term ICP measurements. Our team plans to extend these current ICP devices by integrating a pressure sensor, that can be inserted into a 3D printed implant, with a specialized iOS application in order to wirelessly track data about the intracranial pressure. Our project will be guided as a proof-of-concept project but with the intention to create a device that is not only user-friendly but will also advance ICP telemonitoring techniques.

Paper Selection

Selected Paper: "Long-term telemetric intracranial pressure monitoring for diagnosis and therapy optimisation of idiopathic intracranial hypertension"

Authors: Victor F. Velazquez Sanchez, Giath Al Dayri & Christoph A. Tschan

Journal: BMC Neurology (2021)

Through our project work, the main concept that we are trying to prove is the potential of a wireless device for long-term ICP monitoring. The background literature that we chose is a recent publication on long-term telemetric intracranial pressure monitoring. This literature utilizes a recently developed ICP monitoring device that allowed the authors of this literature to conduct their study. Their work using this device will assist us in analyzing how to design a wireless system that can improve telemonitoring procedures both for the patient and the physician.

Technical Summary

This paper details how researchers have worked to improve the diagnosis and subsequent treatment of idiopathic intracranial hypertension (IIH). By using the NEUROVENT® P-tel System for long term ICP monitoring, researchers were able to hypothesize potential adjustments to IIH guidelines. This method is said to be superior to other simpler approaches based on its ability to provide long-term ICP monitoring and provide a higher correlation of ICP values to the patient's usual activities. This approach is also associated with a potential decrease in risk of infection compared to open systems with cable connection.

Long-term ICP monitoring has 2 comparable settings: home–monitoring and home-telemonitoring using the NEUROVENT® P-tel. Both settings involve the P-tel catheter being surgically implanted. However, the frequency at which the patient must be presented in an outpatient clinic for reading the device determines whether it's home-monitoring or home-telemonitoring. The two settings are required due to limited storage capacity of the data logger unit. In the Home-Monitoring setting, once the device storage is full, the data needs to be transferred or analyzed by an attending physician and old data will be deleted. This process involves the patient going to the outpatient clinic. In contrast the Home-Telemonitoring setting eases the burden of regular outpatient visits with a portable computer and pre-installed software for data transfer after it reaches full capacity.

NEUROVENT® P-tel, the ICP monitoring system consists of a below-the-scalp fully implantable unit and a Silicon membrane, acts as a piezoresistive pressure transducer, and a microchip for data processing. For analysis, a documentation sheet using Raumedic DataVew software for ICP curves over time and amplitudes. Regardless of the settings, both the patient and the physician can see the ICP visuals as seen in Fig. 1. These monitoring sessions found using the TeamViewer software tell the patient and physician about follow-up and treatment optimisation for further ICP monitoring sessions.

By the end of the paper, it was determined that the diagnosis of IIh was confirmed in 18 out of 20 patients. The optical adjustment of the implanted shunt valves was achieved with an average valve opening pressure of 6.3 ± 2.17cm H_2O for differential valves. As anticipated, the Home-Telemonitoring reduced outpatient visits when compared to Home-Monitoring with an average of 3.1 and 4.3 visits respectively. There were no complications reported with the inserting of the P-tel catheter.

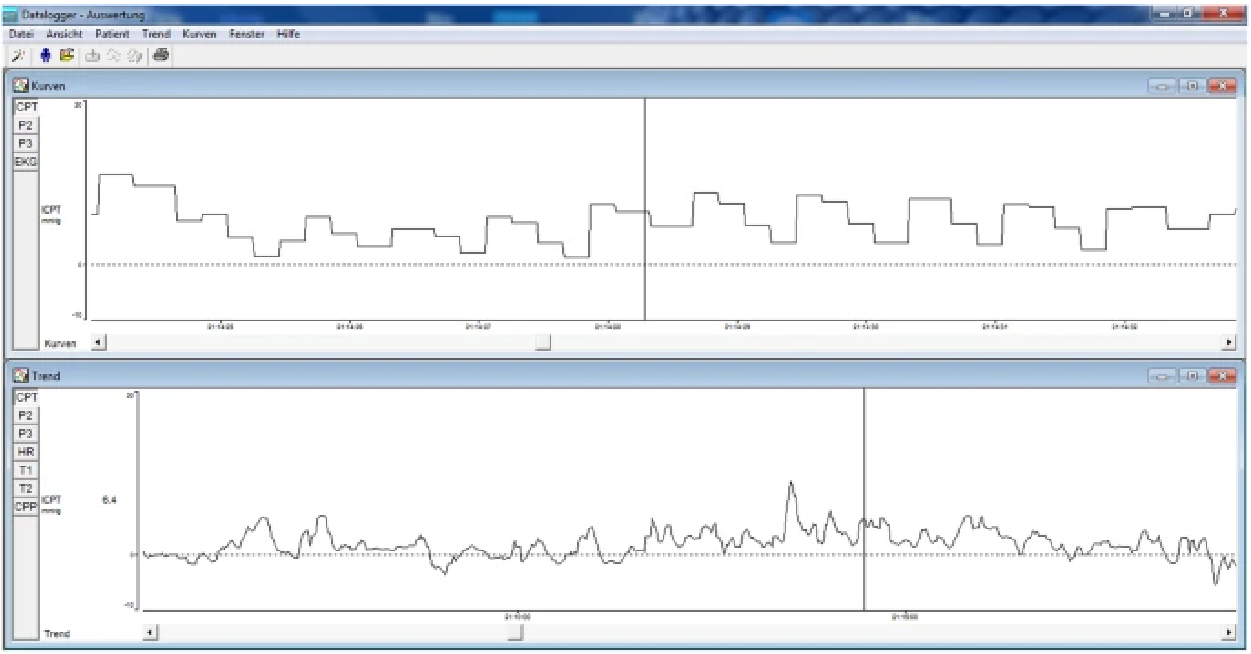

Fig. 1: Remote analysis of ICP measurement curves of a patient with suspected IIH, utilizing TeamViewer software. Screenshot from the physician's PC.

Critical Assessment

Strengths: This paper clearly demonstrated the many advantages of ICP home-telemonitoring when compared to ICP home-monitoring. Since home-telemonitoring provides larger amounts of ICP measurement data without interruption (i.e. without having to continuously go to a clinic), telemonitoring has the potential to provide smoother long-term monitoring. In addition to the advantages of home-telemonitoring, the paper also provides discussion on the setbacks of home-telemonitoring (for example, the fact that it required extensive training for how to manage the software and hardware elements). These points were beneficial in our own discussion on how our design could improve telemonitoring for both the patient and physician.

Weaknesses: This paper conducted this study with a small sample size (n=20) that causes the overall results from this work to not be enough to make definite conclusions on any long-term elements of the hardware (for example, the long-term safety of the catheter). Furthermore, within the sample size used, dividing of participants utilizing the home-monitoring or home-telemonitoring setting was not randomized. Instead, it had been decided on a case-by-case basis based on a participant's proximity to the clinic or ability to use the software and hardware system. Lastly, the ICP timeflow for each participant differed in various aspects such as the duration of usage of the catheter implantation (ranging from 17 days to 1554 days) or the type of IIH therapy used (though the paper did focus more on the implantation and adjustments of VP shunts).

Possible Future Work: The authors do acknowledge the small sample size used in their work and expressed interest in future work that could be combined with the data resulting from this cohort. They additionally hope for future work to determine long-term safety of the overall system implantation. Another possible future work could be to utilize an ICP monitoring system that was noninvasive (since this work used a system with a below-the-scalp implantable unit) and see if IIH can be similarly confirmed or excluded. With an ICP monitoring system that is noninvasive, it might lend itself to lessen a few safety concerns the authors had with the system they used in this work.

Relevance & Conclusion

As previously mentioned, our project will be focusing on the implementation of long-term ICP monitoring to aid in monitoring a patient's pressure levels in daily activities postoperative. Although we are developing the device, this paper was extremely relevant to our background stage of the project centering around the evaluation of different improvements to telemonitoring. This paper had additionally provided us with a few takeaways. First, this study utilized two monitoring settings: home-monitoring and home-telemonitoring. Both settings required the Datalogger that collected ICP data to be transferred to a computer and then cleared frequently throughout its usage due to the limited capacity of the Datalogger. This became a great hindrance to the flow of using the system, especially to those who had to go to a clinic for the data to be transferred and cleared. This is particularly relevant to our use of Bluetooth as we can consider effective ways of data storage on the software end.

Lastly, the telemonitoring system used in this work was complicated and required extensive training for the patients, both with its software and hardware components. Since the aspect of home-telemonitoring focuses both on the ability for long-term monitoring as well as the comfort and ease of integration of the system into a patient's daily life, having a device/system that is user-friendly and doesn't require extensive training to use could be beneficial to improving telemonitoring techniques. We plan to continuously approach our hardware and software components of the ICP monitoring device with the user in mind so that we may develop a system that can be used by both the patient and the physician.

References

1. Velazquez Sanchez, V.F., Al Dayri, G. & Tschan, C.A. Long-term telemetric intracranial pressure monitoring for diagnosis and therapy optimisation of idiopathic intracranial hypertension. *BMC Neurol* 21, 343 (2021). https://doi.org/10.1186/s12883-021-02349-8