

MEDICAL PREMISE

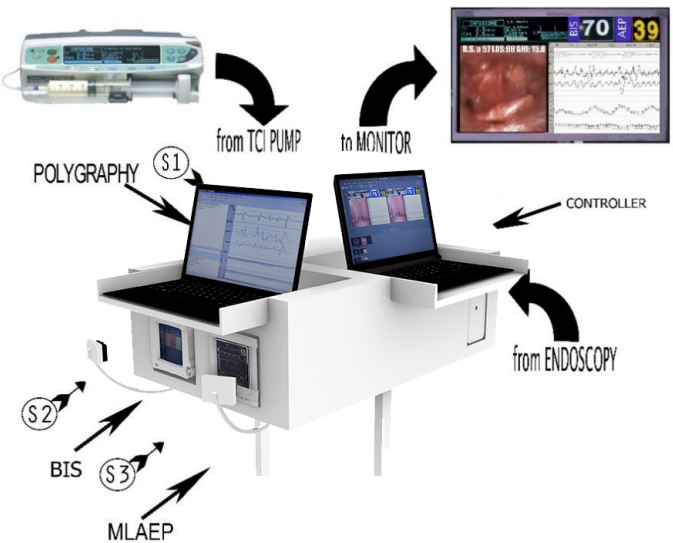
Drug Induced Sleep Endoscopy (DISE) improves the diagnosis and treatment of Obstructive Sleep Apnea (OSA). Our research program aims to improve the reliability of DISE through a technological upgrade called 5 Video Streams Experimental System (5VsEs®) which consists in making possible the ergonomic representation "all at glance" on a single monitor of all the decision-making parameters essential to the operator during the execution of the DISE.

These parameters will then be fully stored. (a)

Secondary objective of our study was to analyze the level of sedation through an alternative method to the "gold standard" Bispectral index (BIS). In the prototype aDISE we used for the first time in DISE the Middle Latency Auditory Evoked Potential (MLAEP) expressed by the index MLAEPi. In a recent study we recruited 99 patients affected by OSA as defined by the American Academy of Sleep Medicine and during DISE we recorded the following parameters in parallel: endoscopic patterns, polygraphic recording pharmacokinetic parameters, MLAEP index (MLAEPi) and BIS index.

These parameters were simultaneously shown on a single monitor and videotaped for post analysis and research purposes using the 5VsEs®

We have described how the full and continuous multi-parametric monitoring and recording improve the management and safety of DISE and any post-analysis and that the Middle Latency Auditory Evoked Potential index is an effective alternative to the BIS index. (b) (1)



WITHIN THE 5VSES® @, THE FOLLOWING THREE PERSPECTIVES ARE CLEARLY RECOGNIZABLE:

The operator side of the 5VsEs® machine is equipped with a device for monitoring online polygraphy "Embletta Gold®" (source 1 - S1). The BIS and AEP instruments are positioned on the same side on which 2 cameras (S2), (S3) with HD record the parameters in HD resolution. The signal from (S1) is sent via HDMI to the HD Video- Grabber with 1080p resolution. This level of resolution allows an optimal reading of the numerical values of the graph generated by the polygraph.

An additional HDMI Video-Grabber is housed in the back, through which the signal from the endoscope processor (S5) is acquired in real time, and is acquired via the HDMI port with Full-HD 1080p quality. Thanks to this resolution it is possible to oversize the video to better evaluate the endoscopic pattern. This is a substantial improvement on the already existing technology that combines polygraph and video.

HD video signals from (S2), (S3) are transmitted via USB 3.0 HUB to the central video processor (*). The 5VsEs® is equipped with a Wi-Fi switch / router through which the video signal (with 720p resolution) from the Wi-Fi camera placed on the TCI-Pump (S4) is acquired. On the left side (patient side) there are instrumentations that will be used on the patient (body equipment: headphones and transducers for MLAEP and transducers for BIS, Embletta polygraphic recorder and related sensors (such as nasal cannula, pulse oximeter, sensors for the abdominal and thoracic bands).

On the right side, the 5VsEs® is equipped with the video control device and the Telestream Wirecast® software which will integrate the video signals (merging) coming from the S1, S2, S3, S4 and S5 sources. This software creates the final vision ("everything at a glance" strategy) or the result from a composition of signals is transmitted on a single monitor. The same control device will also take care of digital recording on an external storage device for later analysis by the team and for legal data storage.

In summary, the most important and exclusive objectives we have achieved with 5VsEs® @ are:

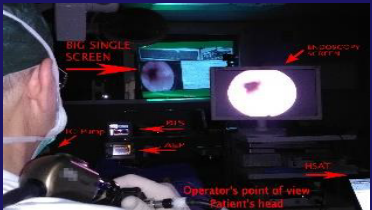
To produce a single video recorded in HD instead of having subsequent video aggregation. This video represents the entire procedure and in this way the video cannot be manipulated by editing, so it is ideal for both scientific evaluation and as legal documentation; the different video latencies of the five types of instruments in the latest version of 5VsEs® @ have been so reduced as not to interfere with the delicate manipulation required by the operator during DISE.

(1) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7345775> - A New Technological () TAKEN FROM THE PAPER " A New Technological Advancement of the Drug-Induced Sleep Endoscopy (DISE) Procedure: The "All in One Glance" (**) this technology has been further implemented by the video over IP casting protocol which allows to reach resolutions up to 10 80p also for BIS and MLA E P i

OPERATION ROOM

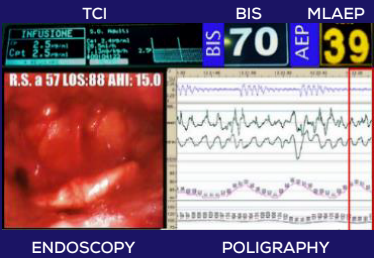


Contrary to the current DISE standard, the "all at a glance" strategy allows for faster and more effective interpretation of all simultaneous parameters during the DISE procedure, improving diagnosis.



5VsEs® provides a recording for a complete post-analysis, very useful for every research field in DISE as well as legal and educational benefits and facilitates the multi centres clinical study.

5VsEs® monitor



5VsEs vs. standard technology performance

5VsEs vs. Standard Procedure	5VsEs	Standard
Documentation of pharmacokinetics-pharmacodynamics profiles	YES	NO
Documentation of the observation window	YES	NO
Documentation useful for multicentric studies	YES	NO
Recovery of lost data during data collection, useful for research purposes	YES	NO
Statistical analysis thanks to data collection confidence (uneditable video documentation)	YES	NO
Medical-legal documentation more complete	YES	NO
Improvement of education and teaching aspects	YES	NO
Efficient telemedicine	YES	NO

5VsEs® improves diagnosis and research by improving the ergonomics of use of instruments and post-analysis. 5VsEs® was designed to solve some problems with the method, including endoscopic pattern classification methods, drug infusion techniques, etc.

CONCLUSION

The 5VsEs @ @ project, born for a specific experimental request, seems to respect the objective of making possible a safe post-analysis in every field of research in DISE and, moreover, shows an unexpected clinical update in the perception of the decision-making parameters during the execution of the procedure that translates results in an easier identification of the DISE observation window.

The complete recording of the procedure provided by the single monitor 5VsEs facilitates telemedicine, the teaching moment and the performance of the team, the medico-legal documentation and, above all, every research.

Taking these aspects into consideration, it is clear that the 5VsEs project facilitates in particular multicentre studies and therefore discussion on the still open issues regarding DISE.

The first experimental data that the 5VsEs instrumentation provided us is the documentation of the response modalities during the DISE of the MLAEPi method already in use in Anesthesiology and Intensive Care.

The 5VsEs@@ machine therefore seems to be a technological advancement and valid alternative to the current standard in DISE in terms of ergonomics and guarantees accurate and integral documentation, essential for post-analysis, teaching, medico-legal documentation and, above all, for research.



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5VsEs[®]

5 Video streams Experimental system

Experimental system with five video streams for carrying out the DISE procedure



MADE IN ITALY