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In-vitro tests of 123 adjustable valves (10 designs)

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Background

Adjustable differential pressure valves (AV) have been inaugurated by Bush & Matson in the early fifties and Kuffer & Strub in 1969. More recently we overview 5 historical models and 13 concepts resp. prototypes; 12 different designs are on the market, using 6 basic constructions. In 1987 Loayza published the first clinical Sophy-report, we the first Medos-P-experiences in 1990. Especially in Europe the AVs are used in ca. 40% of all shunts, especially in children and NPH. In 1989 bench-tests were inaugurated by Richard and our group, followed by Trost, Schöner, Czsonyka, Eklund and others. The problematic electromagnetic safety of AVs – rarely thematized and underestimated in the early papers – found an increasing interest.

Materials and methods

We investigated in laboratory 79 adjustable Medos, 6 Medos Micro-Valves, 16 Sophy SU8/3, each 1 Sophy Mini SU8/3, 3 Sophysa Polaris, 6 Miethke ProGAV and 2 historical Kuffer-valves. 34 were new, 89 explanted, of them 14 defective (not testable). The most new specimen had long-term-tests (n = 17) up to 500 days and multiple subtests for resistance, pressure-flow, safety (external pressure, reflux, etc). Explanted probes passed selected tests only, but had an inspection with magnifier or microscope. Special subtests were dedicated the adjustability, decentration tolerance (5 directions) and stability in magnetic fields. 16 valves were positioned in a 3-T-MRI over 0.25, 1, 6 and 12 h and tested for adjustability.

Results

Except of the early Sophy-specimen the accuracy of new AV-valves was sufficient. However, many valves showed deviations due to debris/protein, preferably precipitated on the rotors. After successful cleaning failures often were reversible. The pressure-flow-graphs of AV showed similar properties of ball-in-cone-valves with fixed adjustment: With 30 cmH2O in low pressure settings the excessive flow reaches 1500–2000 ml/h, but in the highest adjustments it is still 600–700 ml/h. Over drainage is never excluded. – After 3-T-MRI 6/12 Medos-P showed failures in adjustability, preferably in high settings; 4 Sophysa remained adjustable.

Conclusion

In Medos and older Sophysas the fine-tuning of opening pressure and other advantages are counterbalanced by risks of over drainage even in the highest settings and unintended disadjustments. Medos-P can be irreversibly chanced in 3-T-MRI. The third generation (Miethke Pro-GAV, Sophysa Polaris) avoids these problems.