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The Use of the CUSUM Chart Method for Surveillance of Learning Effects and Quality of Care in Endovascular Procedures

L. Calsina, A. Clará*, F. Vidal-Barraquer

Vascular Surgery Department, Hospital Del Mar, Universitat Autònoma de Barcelona, Barcelona, Spain

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Abstract *Introduction:* Quality of care and learning effect surveillance are two mandatory responsibilities within a changing therapeutical paradigm. We aimed to evaluate the feasibility and value of CUSUM chart method in assessing performance in consecutive endovascular procedures done by vascular surgeons of a single department on aorto-iliac, femoropopliteal and renal artery occlusive disease.
Material and method: Data were collected in 405 consecutive patients, scheduled for endovascular intervention of aorto-iliac ($n = 131$, 32.3%), femoropopliteal ($n = 142$, 35%) and renal artery ($n = 132$, 32.7%) occlusive disease during a 6-year period. Quality indicators included inability to cross the lesion, peri- and post-procedural complications and significant residual stenosis or occlusion at 1 month. CUSUM curves were generated for each territory globally and according to each quality indicator. The relevance of curve upward inflections was evaluated with Fisher's Exact Test.
Results: Failure to cross the lesion occurred in 6.9% (aorto-iliac), 10.6% (femoropopliteal) and 2.3% (renal) of patients. One-hundredth twenty aorto-iliac, 127 femoropopliteal and 132 renal angioplasties were finally performed. Peri- and post-procedural complications appeared in 14.5% (aorto-iliac), 9.2% (femoropopliteal) and 2.3% (renal), while significant residual stenosis or occlusion was seen in 0.8%, 4.9% and 2.3% of patients, respectively. Aorto-iliac CUSUM curve showed two upward inflections at the beginning and the end of the period, both associated with peri- and post-procedural complications ($p = 0.002$ and $p = 0.0013$) and the latter also with failure to cross the lesion ($p = 0.009$). Femoro-popliteal CUSUM curve moved progressively upward during all the period, initially related to peri- and post-procedural complications ($p = 0.038$) and later to failure to cross the lesion ($p = 0.004$). Renal CUSUM curve didn't show any upward inflection during the analysed period.
Conclusion: CUSUM curves are an excellent tool for measuring learning effect and quality of care within a changing paradigm, such it is the case of endovascular interventions. Curve

* Corresponding author. Tel.: +34 932483223.
E-mail address: aclara@hospitaldelmar.cat (A. Clará).

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upward inflections can be further interpreted according to the type of "failure" thus helping to evaluate their underlying causes.

Endovascular procedures are quickly replacing open surgical repair as the first revascularisation choice for most peripheral arterial occlusive disorders. This transition towards endovascular techniques is being characterised by the development of new materials, changing indications and the need to acquire new skills within a frame of uncertainty about the durability and costs of such interventions. Importantly, there is a tacit commitment among professionals to keep efficacy and safety competitive in relation to open surgery. Within this paradigm shift, quality of care and learning effect surveillance of endovascular procedures have become two mandatory responsibilities of vascular specialists.

A first step towards measuring the learning effect and quality of care in endovascular procedures is to select quality indicators. Patency, survival and peri- and post-procedural complications have long been regarded as the main outcome measures of vascular reconstruction, although more recently quality of life, geriatric scales or economic analyses[1–5] have been used as quality end points as well. In addition, the ability to complete the endovascular procedure, basically to cross the occlusive lesion, may be considered as a new quality indicator.

Time-series analysis methods report graphs of changes in outcome rates over time and may seem particularly promising for monitoring quality indicators. Among these, cumulative sum (CUSUM) charting,[6–11] developed during World War II as a quality control test in munitions production lines,[12] is a visual method that allows to easily establish whether a production process is "in control" or has become "out of control". CUSUM charting has been found effective for measuring and monitoring surgical outcomes,[13–19] yet to our knowledge little attention has been paid to this methodology for monitoring performance in endovascular procedures.

The Vascular Surgery Department of the Hospital del Mar, Barcelona, Spain, has a continuously fed database of diagnostic and interventional procedures done by vascular surgeons in an endovascular suite. The objective of this study was to determine whether CUSUM charts could be used to identify changes in three quality indicator rates (ability to cross the lesion, peri- and post-procedural complications' rate and 30-day patency) in endovascular revascularisation procedures on aorto-iliac, femoropopliteal and renal arterial occlusive disorders over a 6-year period.

Patients and Methods

Between June 2003 and December 2009, 405 consecutive patients with aorto-iliac ($n = 131$, 32.3%), femoropopliteal ($n = 142$, 35%) or renal ($n = 132$, 32.7%) artery occlusive disorders (stenosis or occlusion) were scheduled for intervention at the endovascular suite of the Hospital del Mar, Barcelona (Spain), equipped with a Siemens AXIOM Artis equipment.

All procedures were performed under local or regional anaesthesia by a senior endovascular expert (F.V.B.) or by other less endovascularly experienced attendant vascular surgeons, or residents, directly supervised by him. By the time the endovascular suite was built (June 2003), the team's accumulated endovascular experience in such territories with a portable C-arm X-ray device in the operating room consisted of 97 aorto-iliac and 55 renal cases. Femoropopliteal endovascular procedures were initiated within the period of study.

For each patient demographic (age and sex) datum, artery occlusive disease location, procedural characteristics (access site, technique and material) and peri- and post-procedural quality indicators (inability to cross the lesion, peri- and post-procedural complications and significant residual stenosis or occlusion at 1 month) were collected from clinical charts and entered into a Statistical Package for Social Sciences (SSPS) database.

CUSUM charting

CUSUM curve represents the consecutive performance of an individual or a team displayed as a line chart with the *X*-axis representing the consecutive series of procedures and the *Y*-axis representing the CUSUM score. Mathematically, the CUSUM score is defined by the cumulative sum of $X_i - X_o$, where X_i represents the success or failure of each consecutive procedure. In our model, a score of '0' for each success and of '1' for the occurrence of a quality indicator (inability to cross the lesion, peri- or post-procedural complication or significant residual stenosis or occlusion at 1 month) were assigned to each endovascular attempt. X_o, on the other hand, represents the procedural inherent risk, that is, the risk related to the nature of the procedure, which is estimated from published work. A procedural inherent risk (X_o) of 0.12 (12%) was thus assumed for both aorto-iliac and femoropopliteal endovascular interventions and of 0.05 (5%) for the endovascular treatment of renal artery stenoses.[20–22]

The basic principle of the CUSUM curve is that of reward or punishment with each consecutive attempt, according to the inherent risk of the procedure. In our model, for example, the occurrence of a quality indicator in each aorto-iliac or femoropopliteal endovascular procedure accounted for an $X_i - X_o = (1-0.12) = +0.88$ (upwards) inflection in the curve, whereas each success determined an $X_i - X_o = (0-0.12) = -0.12$ (downwards) inflection. In a scenario in which the real procedural risk equals its theoretical risk, for instance, a consolidated procedure without a learning effect at play, downward inflections would compensate upward ones and the CUSUM curve would run roughly parallel to the *X*-axis, whereas, for any real procedural risk over its inherent risk, the CUSUM curve would move progressively upwards.

Curve upward tendencies may reflect a learning process, case-mix, new indications or changes in the procedure, among other causes; hence, further CUSUM sub-analyses were done for each territory, taking into consideration only one quality indicator (inability to cross the lesion, peri- or post-procedural complications or significant residual stenosis or occlusion at 1 month). For each of these sub-analyses, one-third of the inherent procedural risk (X_o) associated with each territory was assumed.

Statistical analysis

Statistical comparisons between a team's experience and the ability to improve quality indicators were performed with Fisher's exact test. Cut-off values were chosen according to the points of inflection revealed by the plots. A p value of 0.05 or less was considered statistically significant.

Results

Among the 131 patients (mean age 67.8 years, 93.8% male) scheduled for an aorto-iliac endovascular procedure for stenotic or occlusive disease, 120 angioplasties (117 with stent) were finally performed, thus accounting for a 6.9% rate (nine patients) of uncompleted procedures (inability to cross the lesion). Peri- and post-procedural complications (Table 1) were seen in 19 patients (14.5%) and significant residual stenosis or occlusion at 1 month in one case (0.8%).

Among 142 subjects (mean age 74.1 years, 57.8% male) with femoropopliteal stenosis or occlusions, 127 angioplasties were done, of which 119 were with stent. There was a 10.6% rate (15 patients) of uncompleted procedures (inability to cross the lesion). Peri- or post-procedural complications occurred in 13 patients (9.2%) and significant residual stenosis or occlusion at 1 month in seven cases (4.9%).

Finally, among those 132 patients (mean age 66.9 years, 73.3% male) scheduled for a renal artery intervention, 129 angioplasties, 109 with stent, were performed. Uncompleted procedures accounted for a 2.3% (three cases), peri- or post-procedural complications occurred in 2.3% (three cases) and 1-month patency was 97.7%.

CUSUM charts

Aorto-iliac CUSUM curves (Fig. 1) showed two upward inflections: one at the beginning related to peri- and post-procedural complications and another one at the end of the period of study associated with both peri- and post-procedural complications ($p = 0.002$) and inability to cross the lesion ($p = 0.013$).

The femoropopliteal CUSUM general curve (Fig. 2) showed a continuous upward tendency all over the period of study. When specific CUSUM charts were plotted, however, the initial upward tendency was seen to be associated with peri- and post-procedural complications ($p = 0.038$), while the late one was related to inability to cross the occlusive lesion ($p = 0.004$).

Finally, the renal CUSUM curve (Fig. 3) did not show any upward or downward inflection at all over the 6-year period of study. Further, CUSUM sub-analysis curves for each quality indicator did not provide additional valuable information.

Discussion

Our study has shown the successful application of a continuously updated, monitoring technique for the evaluation of the performance of endovascular procedures in peripheral arterial occlusive disease. Over the 6-year period of study, several time intervals of lower-than-expected performance were identified by CUSUM curves. Further analyses according to each type of quality indicator determined that both inabilities to cross the occlusive lesion and peri- or post-procedural complications, but not immediate patency results, were responsible for such upward curve tendencies. These quality indicators can be related to individual or team lack of experience, changes in materials or in the endovascular procedure or to an extension of indications to more complex patients. Further prospective studies are needed to improve our understanding of the underlying causes of downshifts in the performance in novel procedures.

The inclusion of 'inability to cross the lesion' as a quality indicator may be problematic and deserves some comment. Obviously, it may indicate operator's lack of experience, collective uncertainty among vascular specialists or the insufficiencies of existing materials and devices. Yet, sometimes 'inability to cross the lesion' may be also deliberate when the operator decides not to force a guidewire re-entry because a segment of patent artery

Table 1 Peri- and post- endovascular procedural quality indicators in the population of study.

	Aorto-Iliac cases (%)	Femoro-Popliteal cases (%)	Renal cases (%)
Peri- or post-procedural complications			
Perforation	2 (1.5%)		
Dissection	6 (4.6%)	1 (0.7%)	2 (1.6%)
Occlusion	2 (1.5%)	3 (2.1%)	
Pseudoaneurysm	7 (5.3%)	6 (4.2%)	
Vasovagal	1 (0.8%)		
Bleeding		1 (0.7%)	
Anaphylaxis			1 (0.8%)
Death	1 (0.8%)	2 (1.4%)	
Significant residual stenosis or occlusion at 1 month	1 (0.8%)	7 (4.9%)	3 (2.3%)
Failure to cross the lesion	9 (6.9%)	15 (10.6%)	2 (2.3%)

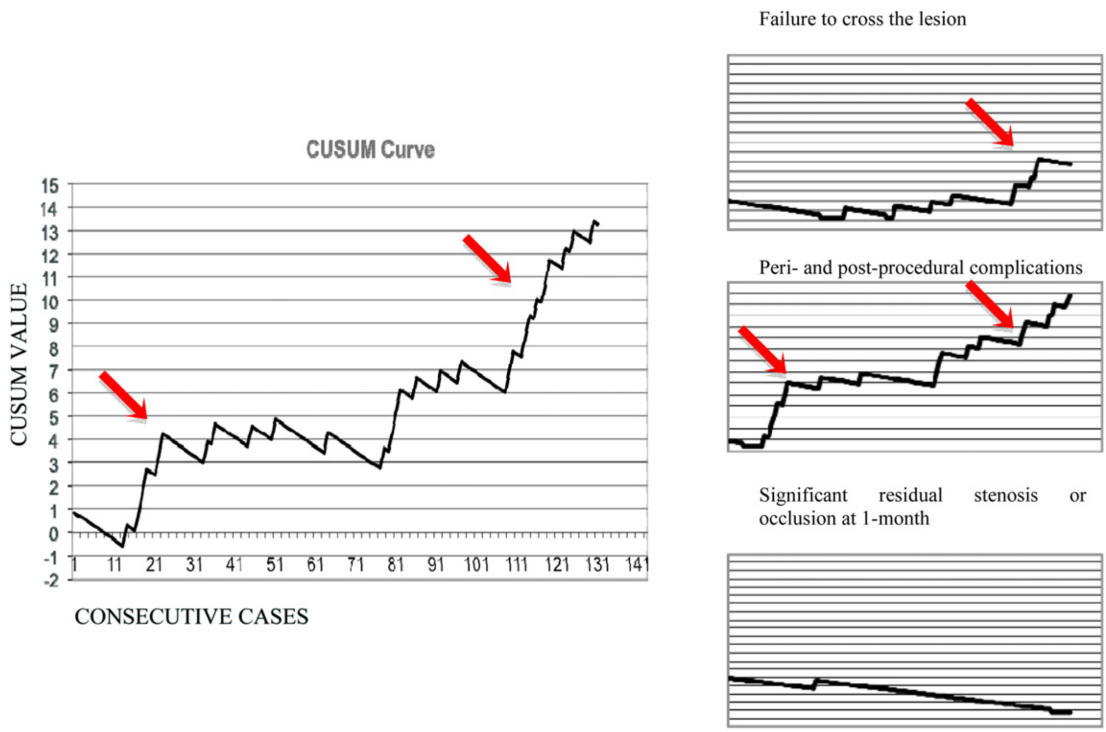

Figure 1 CUSUM curves of aorto-iliac endovascular interventions: General CUSUM curve shows two upward inflections (arrows) whose cause is revealed by the specific curves resulting from sub-analyses with each quality indicator.

can be compromised and the surgical revascularisation alternative jeopardised, as it is considered, for instance, at our institution. Most of these "unsuccessful" attempts can be done with no or very little harm to the patient at the time of obtaining the angiographic data necessary for surgical planning. However, as the underlying causes of not crossing the lesion, whether deliberate or not, can be difficult to elucidate in real practice, it makes sense to keep this variable as a quality indicator of endovascular performance.

The knowledge of the inherent risk associated with each type of endovascular procedure, a requisite of the CUSUM methodology, is another problematic issue that deserves additional comments, first, because a procedural risk

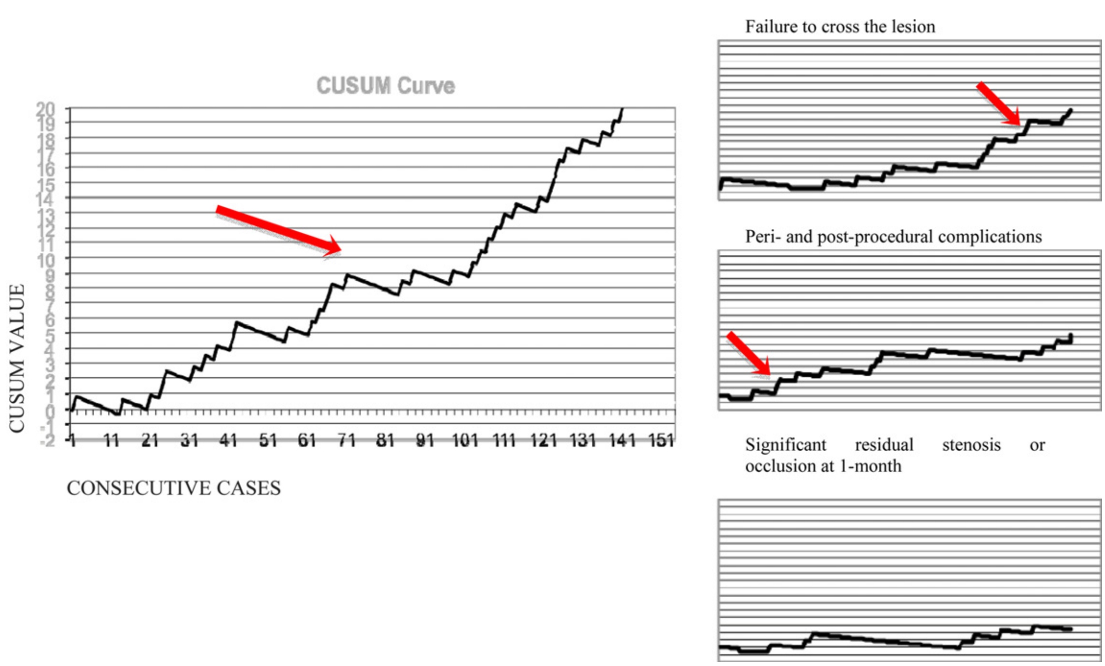

Figure 2 CUSUM curves of femoropopliteal endovascular interventions: General CUSUM curve shows a continuous upward inflection whose cause is revealed by the specific curves resulting from sub-analyses with each quality indicator.

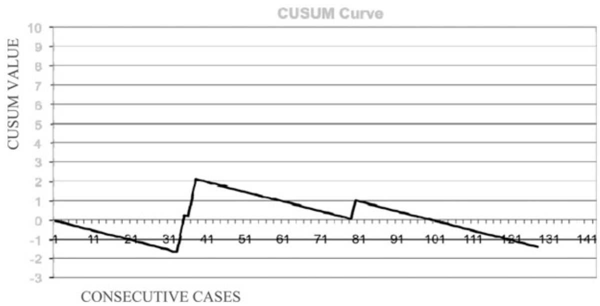

Figure 3 CUSUM curve of renal endovascular interventions: No up- or downward inflections were seen in the general or specific (not plotted) CUSUM curves thus revealing a steady performance within accepted standards of risk.

including the inability to cross the lesion, peri- and post-procedural complications and 30-day patency, is seldom reported in the literature. While patency results are universally described, the amount and type of peri- and post-procedural complications are described with great heterogeneity among studies.[23–31] Needless to say that unsuccessful lesion crossings are only reported in some prospective studies with cases collected on an intention-to-treat basis. The inherent risk for each generic type of endovascular procedure was thus extrapolated from literature.[20–22] After viewing our CUSUM curves, however, these inherent risks were found to be appropriate for our analyses of aorto-iliac and renal endovascular cases, but probably were too optimistic for our femoropopliteal cases, in which the CUSUM curve showed a steady upward slope over the whole period of study. CUSUM curves are illustrative of performance when no upward inflections emerge within standard accepted risks or when curve inflections alternate with plateau phases, but are of little value when a steady upward tendency dominates the curve.

The difficulties in choosing an adequate theoretical risk for each CUSUM analysis has been reported to be overcome, not without added complexities, by an adjusted risk associated with the type of procedure and features of the patient.[10,11] Other more simple approaches can be also helpful. For instance, if the assumed risk is first stated at the highest accepted value and the CUSUM curve shows a plateau — thus not illustrative — the risk value can then be moved downwards until curve inflections emerge and further interpretation of changes in performance can be done. A different approach, as it was used in this study, consisted in plotting different CUSUM curves according to each quality indicator, thus helping to understand the underlying causes of performance inflections, as was the case of aorto-iliac and femoropopliteal cases. Renal endovascular CUSUM general and specific curves showed a plateau since the beginning of the study even at minimal assumed risk values. This steady performance within accepted limits can be explained by the predominance of stenotic rather than occlusive lesions and the previous experience of the team in such a standardised and relatively easy procedure.

In summary, CUSUM curves appear to be an important tool for vascular specialists in assessing their endovascular performance using a real-time, simple and visual method adjusted by the inherent risk of the procedure. Curve subanalyses according to predefined quality indicators have shown to be useful in appraising the underlying causes of curve upward inflections. Prospective studies are needed to assess the impact of CUSUM monitoring on endovascular outcomes and to fine-tune the causes of any downward trend in performance.

Conflict of Interest

None.

Funding

None.

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