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Statistical Quality Control Charts for Liver Transplant Process Indicators: Evaluation of a Single-Center Experience

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ABSTRACT

Liver transplantation, the best option for many end-stage liver diseases, is indicated in more candidates than the donor availability. In this situation, this demanding treatment must achieve excellence, accessibility and patient satisfaction to be ethical, scientific, and efficient. The current consensus of quality measurements promoted by the Sociedad Española de Trasplante Hepático (SETH) seeks to depict criteria, indicators, and standards for liver transplantation in Spain. According to this recommendation, the Canary Islands liver program has studied its experience. We separated the 411 cadaveric transplants performed in the last 15 years into 2 groups: The first 100 and the other 311. The 8 criteria of SETH 2010 were correctly fulfilled. In most indicators, the outcomes were favorable, with an actuarial survivals at 1, 3, 5, and 10 years of 84%, 79%, 76%, and 65%, respectively; excellent results in retransplant rates (early 0.56% and long-term 5.9%), primary nonfunction rate (0.43%), waiting list mortality (13.34%), and patient satisfaction (91.5%). On the other hand, some indicators of mortality were worse as perioperative, postoperative, and early mortality with normal graft function and reoperation rate. After the analyses of the series with statistical quality control charts, we observed an improvement in all indicators, even in the apparently worst, early mortality with normal graft functions in a stable program. Such results helped us to discover specific areas to improve the program. The application of the quality measurement, as SETH consensus recommends, has shown in our study that despite being a consuming time process, it is a useful tool.

LIVER transplantation is the preferred option for treating an end-stage organ failure. In the framework of scarce donors and an increasing breath of indications for transplantations, this demanding treatment must be appropriate in ethical, scientific, and financial terms.[1] To accurately assess a liver transplant program, some institutions and scientific organizations have analyzed the process using quality criteria, proposing monitoring to achieve excellence, accessibility, and patient satisfaction.

In the last years in 3 successive consensus conference, the Spanish Liver Transplant Society (Sociedad Española de Trasplante Hepático [SETH]) has recommended definitions of quality, as indicators and their measurements; revised standards; proposed frequencies of measurements and examined usefulness of each indicator.[2] According to the recommendations of the last consensus conference of SETH in 2010, the liver transplant program of The Canary Islands (Spain) has analyzed the quality criteria and indicators seeking to depict its process. The purpose of this study was to analyze the state of our program of cadaveric liver transplantation. Our main objective was to examine fulfilment of the SETH 2010 criteria and indicators within the whole program. As secondary objectives, we sought to know the impact of the learning curve on the quality indicators and also, to assess the applicability of quantitative quality control within our system.

METHODS

The population was consecutive cadaveric orthotopic liver transplantations performed in the Canary Islands from April 1996 to

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December 2010 with a minimum of 6 months of follow-up (June 2011). To evaluate the impact of the learning curve on the program we compared first 100 cases with the last 311 transplant from June 2001 to December 2010. The latter partial series who contrasted with the whole program as the global series.

SETH in 2010 defined the 8 proposed criteria as:

1. Definition of the documents of the process;
2. Definition of areas of responsibility;
3. Definition of resources (structural/professional/services);
4. Definition of activities (candidate evaluation, waiting list management, surgical procedure, postoperative management, follow-up);
5. Definition of protocols as vascular risk factor detection;
6. Evaluation of quality indicators;
7. Definition of information registry; and
8. Definition of the document catalogue.

Thirteen quality indicators were defined under the JCAHO (Joint Commission on Accreditation of Healthcare Organizations) recommendations and 12 out of 13 standards were marked as a references for comparison among programs.

1. *Postoperative mortality:* Percentage of deceased transplanted patients in the hospital stay among total transplantation per period (SETH 2010 recommendation: twice a year). *Justification:* Outcome indicator of candidate evaluation, donor aspects, transplant procedure and postoperative care (Fig 1).
2. *Perioperative mortality:* Percentage of deceased transplanted patients in the first 24 hours after transplantation among the total transplants per period (SETH 2010 recommendation: twice a year). *Justification:* Outcome indicator of candidate evaluation, serious intraoperative cardiovascular events, complete portal thrombosis and others events (Fig 2).
3. *Early retransplant rate:* Percentage of retransplants in the first week after cadaveric transplantation among total transplants per period (SETH 2010 recommendation: twice a year). *Justification:* Quality indicator of postoperative period, technical events, donor–recipient selection.
4. *Long-term retransplant rate:* Percentage of retransplantations excepting the first week among total transplants per period (SETH 2010 recommendation: twice a year). *Justification:* Quality indicator of postransplant and long-term activity for aspects as long-term technical consequences and medical problems (inmunosuppression, relapse etc)
5. *Early reoperation rate:* Percentage of urgent reoperations in the postoperative hospital stay among the total transplants per period (SETH 2010 recommendation: twice a year). *Justification:* Outcome indicator of technical problems and surgical complications even with an adequate initial surgical procedure (Fig 3).
6. *Survival:* Actuarial survival curve at 1, 3, 5, and 10 years of transplanted patients (SETH 2010 recommendation: not defined, once a year in our series). *Justification:* Outcome indicator.
7. *Candidate study in a 1-month space:* Percentage of candidates studied in a time lapse less than one month (accepted or not) among the total evaluated candidates per period (SETH 2010 recommendation: not defined, once a year in our series). *Justification:* Process indicator of candidate selection, and efficiency in medical organization (Fig 4).
8. *Primary nonfunction percentage:* Percentage of patients who develop primary nonfunction (PNF; retransplant or death) among total transplants per period (SETH 2010 recommendation: four times a year). *Justification:* Outcome indicator of coordination, skill and experience of surgical teams and communication.
9. *Nonimplanted grafts rate:* Percentage of nonimplanted grafts after acceptance among the total implantable grafts per period (SETH 2010 recommendation: not defined, once a year in our series). *Justification:* Process indicator of adequate donor acceptance.
10. *Patient satisfaction:* Percentage of satisfied or very satisfied results of a specific inquiry after transplantation (SETH 2010 recommendation: once a year). *Justification:* Outcome indicator of the global medical quality, namely, recipient perception of the quality of evaluation.
11. *Waiting list mortality:* Percentage of drop out candidates due to death or progression among the active waiting list among total candidates on the waiting list per period (SETH 2010 recommendation: once a year). *Justification:* Outcome indicator of waiting list management.
12. *Early mortality with normal functioning grafts:* Percentage of deceased patients during the hospital stay after transplantation with normal graft function among the total transplants per

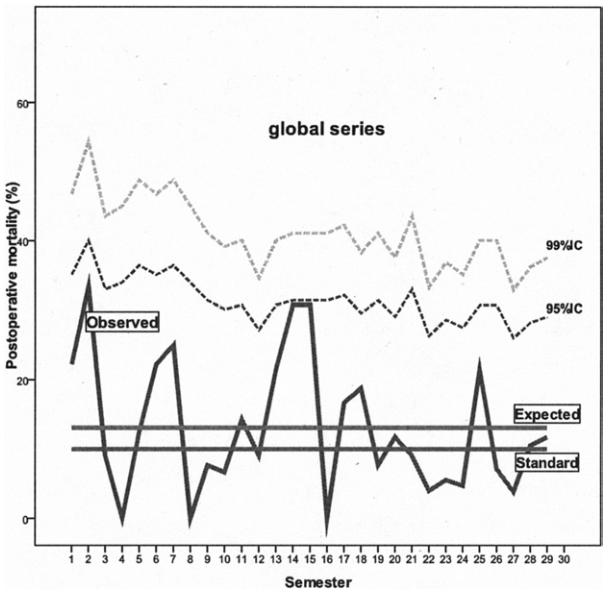

Fig 1. The global postoperative mortality statistic quality control chart expresses the stability of our program and is efficient for detecting peaks of parameters out of standards. The *x*-axis reflects the time from the beginning of the program in semesters. The inferior fluctuated line is the observed postoperative mortality (*y*-axis) in percent. The 2 superior broken lines are the ceiling of our model. The most superior one express the 99% confidence interval, that is, the range of random fluctuation of the indicator; points over this line have a 0.005 occurrence probability. The inferior express the 95% confidence interval, that is, the range of random fluctuation of the indicator; points over this line have a 0.025 occurrence probability. The peaks are not due to accident and are less pronounce as time elapse. Of the two horizontal inferior continuous lines that cross the fluctuate line the more superior is our expected mortality by historical behaviour (13%) and the one below the standard of the SETH (<10%).

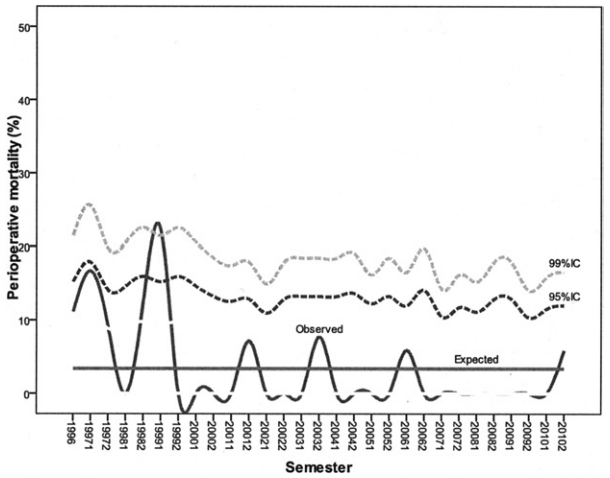

Fig 2. The global perioperative mortality statistic quality control chart. The *x*-axis reflects the time in semesters (twice a year) from the beginning of the program. The inferior fluctuated line is the observed perioperative mortality (*y*-axis) in percent. The 2 superior broken lines are the ceiling of our model. The most superior one express the 99% confidence interval, that is, the range of random fluctuation of the indicator; points over this line have a 0.005 occurrence probability. The inferior express the 95% confidence interval, namely, the range of random fluctuation of the indicator; points over this line have a 0.025 occurrence probability. The peaks are not due to accident and are less pronounce as time elapse. The horizontal inferior continuous lines that cross the fluctuate line is our expected mortality by historical behaviour (1.39%). The standard line of the SETH is not shown due to be nearly coincident wit the observed line (<1%).

period (SETH 2010 recommendation: once a year). *Justification:* Outcome indicator of candidate selection and evaluation (Fig 5).

13. *Long-term mortality with normal functioning graft:* Percentage of deceased transplanted patients with normal graft function among total transplants per period (SETH 2010 recommendation: once a year). *Justification:* Outcome indicator of life conditions and activity of patients.

Normalization and Certification of the Program by ISO 9001:2008

Since 2009, the program has undergone an external quality control, which was independent of and complementary to SETH 2010 recommendations. In this normalization, some criteria were designed exclusively for our program as quality indicators: hospital or intensive care unit (ICU) stay and, warm or cold ischemia time. The data included aspects of satisfaction were used in this study in the case of missing data from the general database.

Data Collection

From April 1996 to present, we have established prospective data collection on graft and patient survivals, and waiting list management as part of the ONT (Organización Nacional de Trasplantes, Spain) and ELTR (European Liver Transplant Registry) registries. Our program participates in both registries. From 2005 (date of the first SETH consensus, published in 2008) to present, some data were prospectively collected because successive consensus meetings modified the indicators, and their measurements. Therefore, necessary unknown data from before this date were retrospectively obtained from medical reports and the database since the beginning of the program.

Data Processing

Indicators are calculated periodically from the data. Visual exploration of the 13 time series indicators and estimation of simple and partial autocorrelation coefficients with a maximum of 7 lags was done to corroborate the random behavior of the time series.

Statistical construction of quality control charts for every indicator in both time sequences included mean values +1.96 standard deviation (SD) and mean+2.58 SD for each period defined to be 2 levels of maximal random fluctuation of indicators. Calculations were performed using IBM-SPSS 19.0 statistical software package (SPSS, Inc., Chicago, Ill) for Windows PC.

RESULTS

The 411 total transplants (408 cadaveric and 3 domino) included in the study were the global series, and the last 311 after the first 100 (learning curve) as the partial series.

The study of the criteria demonstrated that every criterion was fulfilled in our program since 2009, once the ISO normalization and accreditation was established. Before that date, some criteria were not accurately reported. The unique missing criterion was the lack of a specific written

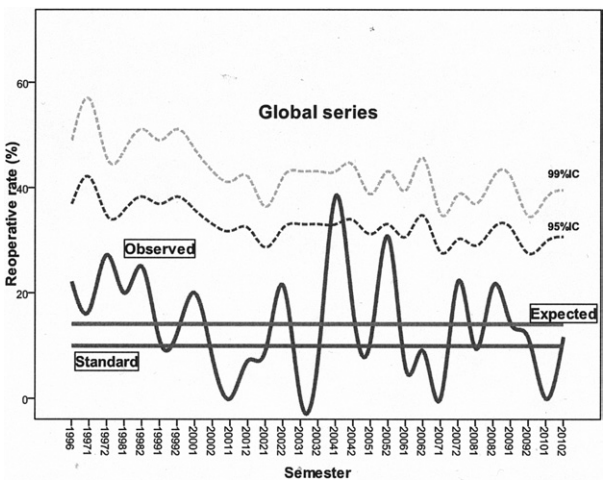

Fig 3. Global reoperative rate statistic quality control chart. The *x*-axis reflects the time in years from the beginning of the program. The inferior fluctuated line is the observed reoperative rate (*y*-axis) in percent. The 2 superior broken lines are the ceiling of our model. The most superior one express the 99% confidence interval, or the range of random fluctuation of the indicator; points over this line have a 0.005 occurrence probability. The inferior express the 95% confidence interval, or the range of random fluctuation of the indicator, points over this line have a 0.025 occurrence probability. The peaks are not due to accident and are less pronounce as time elapse. Of the two horizontal inferior continuous lines that cross the fluctuate line the more superior is our expected reoperative rate (14.15%) and the one below, the standard of the SETH (<10%).

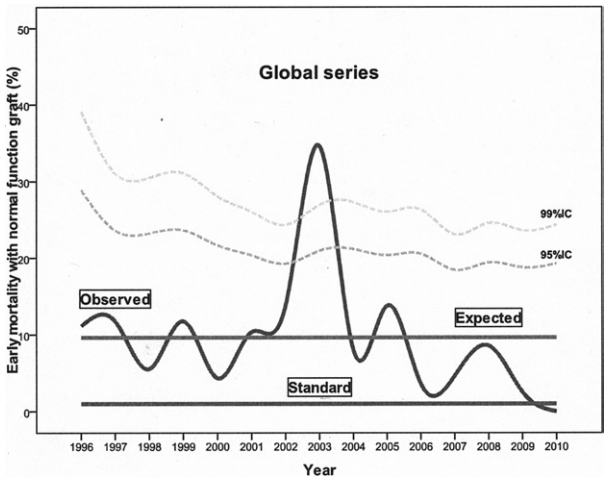

Fig 4. Candidate rate study in 1 month space statistic control quality chart. The *x*-axis reflects the time in years from the beginning of the process of this data (2005). The inferior fluctuated line is the observed. Candidate rate study in 1 month space (*y*-axis) in percent. The 2 superior broken lines are the ceiling of our model. The most superior one express the 99% confidence interval, or the range of random fluctuation of the indicator; points over this line have a 0.005 occurrence probability. The inferior express the 95% confidence interval or the range of random fluctuation of the indicator; points over this line have a 0.025 occurrence probability. Note that the standard of the SETH (>75%) is in between this lines, being our expected data (58.51%) well below the standards but with a clear tendency to its fulfilment.

protocol to detect vascular risk factors after transplantation, although in medical practice transplant patient follow-up included this point in every case. The indicators and standards are shown in Table 1. Some indicators were partially studied owing to missing data within 1-month space indicator candidate study (only available from 2005), and the patient satisfaction or nonimplanted grafts rate (data since 2009).

As shown in Table 1, the main graft and patient survival outcomes were favorable for both series. For every indicator, a control chart was constructed (not shown). Each indicator in the global series was evaluated with this tool to examine the stability of the program. However, in the partial series some indicators did not shown the demanded random behaviour required for use of a statistical quality control chart. Only in 5 among 13 indicators did we observed negative outcomes compared with the SETH standards. In 3 out of these unfavorable results, we showed amelioration in the majority, not only in absolute percentage but also in the control charts (Figures 1 to 5). Full description is given at the bottom of each figure.

Some issues were observed during this study, including a lack of medical definition of PNF or a normal functioning graft; difficulty to calculate some indicators due to confounding explanations such as postoperative mortality or reoperation percentage; extreme time consumption; and recalculation measurements and retrospective data collection—the necessary change of indicators along the 3 consensus forces to collect data retrospectively. The monitoring frequency established by the SETH prevented examining some indicators in control charts and demanding recalculation of some measures over time to apply the statistical method for quantitative quality control.

DISCUSSION

Successful liver transplantation depends on many procedures; candidate evaluation, skill and expertise in the surgical procedure, and ongoing monitoring both in hospital and long term. This paradigm of a complex process is characterized by the multidisciplinary work of various medical specialities, nurses, and other professionals. The aspects produce economic and clinical consequences for in-patient care, society, and medical expertise. Yet, liver transplantation is the treatment of choice for end-stage hepatic disease based upon thorough demonstration of its validity.[1,3] Currently, the serious donor scarcity has evolved into a difficult situation with ethical implications for organ allocation.[1] It is mandatory in this frame to guarantee the best outcomes by each program of liver transplantation.

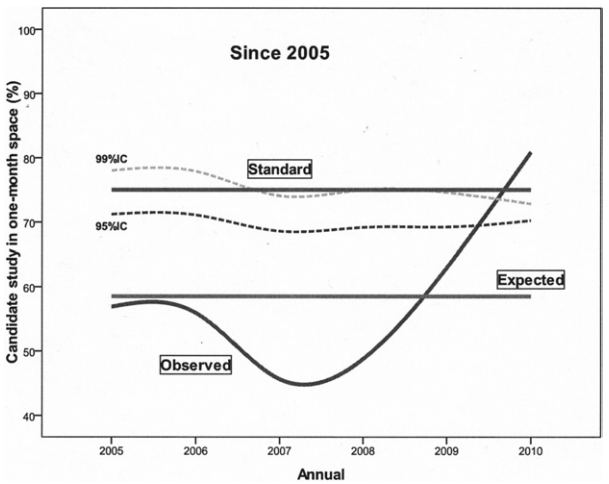

Fig 5. Early mortality with normal functioning graft statistic quality control chart expresses stability and is efficient for detecting peaks of parameters out of standards as shown. The *x*-axis reflects the time from the beginning of the program in years. The inferior fluctuated line is the obtained early postoperative mortality (*y*-axis) in percent. The peaks are not due to accident and are less pronounce as time elapse except for the peak around 2003. The 2 superior broken lines are the ceiling of our model. The most superior one express the 99% confidence interval, or the range of random fluctuation of the indicator; points over this line have a 0.005 occurrence probability. The inferior express the 95% confidence interval, or the range of random fluctuation of the indicator; points over this line have a 0.025 occurrence probability. Of the 2 horizontal inferior continuous lines that cross the fluctuate line the more superior is our expected early mortality (13.04%) and the one below, the standard of the SETH (<10%).

Table 1. Quality Indicators and Standards

Quality Indicator SETH 2010	Global Series (%) n = 411	Partial Series (%) n = 311	SETH Standard (%)
Postoperative mortality	13.03	12.59	<10
Perioperative mortality	3.3	1.39	<1
Early retransplant	0.56	0.27	<5
Long-term retransplant	5.9	5.3	<8
Reoperation	14.2	13.1	<10
Survival (1/3/5/10 years)	84/79/76/65	84/79/76/65	80/75/70/60
Candidate study <30 days *		58.5	>75
Primary non function proportion	0.43	1.13	<2
Non implanted graft†		1.03	0.1
Patient satisfaction†		91.5	>80
Waiting list mortality	13.34	13.08	<15
Early mortality with functional graft	9.63	9.95	<1
Long-term mortality with functional	18.6	14.8	—

*No complete information until 2005.
†No complete information until 2009.

To help the transplant community must this challenge, some institutions in Spain are trying to design measurements that accurately capture improvements in evidence-based care processes. Since 2002 in Andalusia first and from 2005 to present, the SETH has recommended several aspects of the quality of care in liver transplantation.[2] This process has been employed successfully in other areas.[4,5]

The last revised document of the SETH promulgated in 2010 and published recently[2] highlighted the necessity of quality of care control defining controversial aspects such as criteria, indicators and standards to evaluate and monitor Spanish programs of cadaveric liver transplants in a transparent fashion. Our purpose in this study was to monitor our own liver transplant program, which has been active since April 1996 in a low-volume center with a lengthy period to achieve the first 100 liver transplantation (from April 1994 to May 2001) and with a challenging geographical situation that is far away from the mainland and includes seven islands.

The outcomes in our series were favorable in terms of survival (actuarial 1-, 3-, 5-, and 10-year survivals of 84%, 79%, 76%, and 65%), retransplantation rates (early and long term, 0.56% and 5.9%, respectively) waiting list management (mortality 13%.) and PNF rate (0.43%). Each of these criteria were superior to the reported ONT or ELTR results.[6,7]

In relationship to satisfaction (91.5% in our series), we obtained acceptable results only in the last 2 years, so we consider that this point is interesting to monitor in the future. In addition this inquiry has become an important goal objective, as recommended by the Joint Commission.[4]

Despite our good outcomes among classic key quality measures,[1,3,6,7] the SETH consensus has focused on parts of our program that are areas for improvement. Indicators as reoperation, postoperative, perioperative, and early mortality with a normal functioning graft (14.2%, 13.0%, 3.3%, and 9.63%, respectively) are beyond the SETH 2010 standards.[2] No reported comparison with Spanish or worldwide programs is available. There are incomplete reports of some indicators as survival, retransplant rate, perioperative death and others, but in general registries and publications show worse results than our series.[6,7] We believe that perhaps some studies are in process due to the recent publication of the consensus and that it is not possible to derive a fair comparison in the same terms as our series.

Another point of non-quality measurement was the candidate study, which is unacceptably long (58.5%) below the SETH 2010 recommendation (>75%). Again, no comparison with others sources is possible. We are convinced that this new quality approach will permit better control of this part of our program.

Nevertheless, the 5 worst results among the 13 indicators showed improvement during the program, every indicator improved except early mortality with a normal functioning graft. Analysis of these outcomes let us to deduce that ours intraoperative–postoperative procedures can clearly be improved since they were outside the quality standards. The construction of control charts has been useful. This statistical quality control instrument allows us to analyze measures of the program, in such a way that the monitored indicator reflects external causes of disturbance and therefore, may be in some cases be avoidable or controllable.[8–11] With this tool we have assessed objectively the development of our program. Using each indicator, we have explored the trends in our program over time. Those indicators with worse results showed spontaneous improvements; after study of the partial series, several indicators improved, possibly due to progression through the learning curve. Currently, it seems that our program is under control and stable.

In our study, once the learning curve was overcome, statistical quality control charts of indicators helped us to identify parts of the procedure to target for potential amelioration. Not only can we judge our program critically, seeking to detect which degree of quality we have offered in the past and in the present, but also which is our next goal. In the medical process, the utility of normalization and accreditation is far reported.[4] In the case of liver transplantation in Spain, there is no specific accreditation out of the official Health Ministry and its branch, the ONT. With the objective to advance quality in liver transplantation, our program has been submitted to external quality control by a European normalization named ISO 9001:2008.[12]

The design of the quality plan was designed during 2009, executed in 2010 with first outcomes analyzed in 2011. Therefore, with this annual report, another quality control has been established in our program, as complementary to the SETH recommendations. In this planning, patient satisfaction and better coordination aspects are priorities. We consider that this analysis of our program is extremely useful to decide new actions to ameliorate it. Also dynamic

use of these tools allows us to monitor our improvements and the effects of changes in patient outcomes.[9,11]

Changes in the type of indicators as well as the recommended standards over the 6 years, do not provide an accurate reference either among the global and partial series or with other programs. Only some data from the ONT or ELTR and partial information from different hospitals have served us for comparisons.

In summary, further publications of these indicators are necessary to compare liver transplant programs. The frequency and utility of current indicators must be demonstrated in future studies.

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