**Development of the Asystolic Predication Score: A tool to assist shared decision making, in DCD donation through prediction of time to asystole following withdrawal of life sustaining treatment.**

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**Development of the Asystolic Predication Score: A tool to assist shared decision making, in DCD donation through prediction of time to asystole following withdrawal of life sustaining treatment.**

**Abstract**

**Objective.** The aim of this study was to develop and validate a clinical tool to provide probabilities of asystole following withdrawal of life sustaining treatment (WLST) in potential DCD donors in the United Kingdom, which is imperative to shared decision making.

**Design.** A two stage prospective observational cohort study was undertaken. A scoring tool incorporating clinical variables, assimilated to a score on the basis of derived severity was validated. Data were collected at two time points; initial referral and 60 minutes prior to WLST. Cox regression analysis determined overall probabilities of asystole following WLST.

**Setting.** Multi-centre mixed and neurological adult intensive care units in the United Kingdom.

**Patients.** One hundred and sixty three potential DCD donors who underwent WLST were included in this study between 2010-2011.

**Measurements and Main Results.**  Cox Regression demonstrated statistically significant (*p*<0.05) probabilities of asystole using the APS tool. Probabilities of asystole were produced for time points between 0 and 240 minutes. Lower scores have a low probability of asystole occurring within 180 minutes while higher scores have a high probability of asystole occurring at all time points. Potential donors with APS total scores greater than 30 all died within 180 minutes of WLST.

**Conclusion.** The tool provides important information on likelihood of asystole within defined time lines. This ability to predict time lines could be used by clinicians in decision making re: referring potential DCD donors, and through sharing probabilities of donation occurring with family members thereby facilitating shared decision making to underpin informed consent.

**Introduction**

There are approximately 10,000 people in the UK waiting for a transplant of at least one organ and the gap between the supply of organs needed and the demand for organs is increasing.

In view of the growing gap, centres in the UK began to re-explore the potential for DCD donation in the early 2000’s. Donation after Circulatory Death (DCD) is the method of organ donation performed after death has been confirmed on the basis of permanent cardio-respiratory arrest [1], and whilst most centres initially focused on retrieving only kidneys from DCD donors with the successes of the DCD kidney transplants, other organ transplants began to be carried out in the UK [2]. Currently DCD donors are considered as potential lung, liver, pancreas, kidney and tissue donors. There is an expectation that this type of donation will lead to an increase in organs for use in transplant operations and figures appear to support this expectation with DCD numbers increasing from just 42 DCD donors in 2001-02 to a high of 436 donors in 2011-12 [3]. Furthermore figures from the national audit of potential donors in the UK [3] show that for 2011-2012 DCD donors accounted for 40% of the deceased donor pool, which is one of the highest DCD donation rates in the world. It is therefore clear that DCD could impact on the current shortage of organs for transplant operations.

However, despite the successes of the DCD programme in increasing the donor pool and number of transplants taking place unresolved problems persist. A particular problem is the difficulty of predicting which potential donors referred for assessment will become asystolic within a pre-specified timeframe following WLST [4, 5].

**Background**

UK guidance on DCD donation has been developed by the Intensive Care Society in collaboration with the British Transplantation Society and the Department of Health [6]. The guidance describes the process for DCD donation, acknowledging that not all patients will become asystolic within the necessary timeframes to enable successful facilitation of the retrieval process. The UK National Organ Retrieval Service (NORS) Standards state that the potential donor will be monitored for up to 180 minutes following WLST awaiting the onset of functional warm ischaemia and/or irretractable cardiac asystole. In some cases where it is deemed appropriate and logistically possible, this may be extended to 240 minutes.

However even with these timelines being in place 40% [3] of potential DCD donors do not become asystolic within these boundaries and therefore do not donate organs. This situation has contributed to a perceived reluctance amongst clinicians to refer all patients undergoing WLST for assessment as potential donors. This may in part be based on questions regarding the benefit to the patient of this intervention and findings reporting an increase in the emotional distress and disappointment experienced by family members when donation does not proceed [7] [8, 9]. Non proceeding DCD donation also has an economic consequence due to the resources required in facilitating this process. These issues have contributed to a debate regarding the ethics of facilitating potential donors when the likelihood of asystole within the required timeframes is low and therefore donation is unlikely to occur[10] [11].

The issue of predicting asystole is therefore an increasingly important issue.

The clinical impact of not being able to predict the time to asystole from WLST has engaged the South West Organ Donation Services Team (SWODST), as this team has to date facilitated the highest number of proceeding DCD donors in the UK with 56 donors for 2011-2012. However, 38% of all potential DCD donors did not proceed to asystole within the agreed timeframe following WLST, resulting in a non proceeding donation. In response to this clinical barrier to DCD donation and distress to family members, the SWODST brought together a working group to systematically develop an asystole prediction scoring (APS) tool. The aim was that the tool could be used by clinicians so that the probability of donation proceeding based on the time from WLST to asystole occurring could be included in discussions underpinning shared decision making.

Involving the family and clinical staff in a shared decision making process using a tool to assess probabilities of asystole occurring within the defined timeframes will empower [12] all those involved to make informed decisions as both clinicians and family members will be better informed regarding what to expect and can make plans and decisions accordingly [13]. It is likely that this will impact on clinician’s confidence in discussing WLST, as part of end of life care, as they can use the tool as a rationale. In view of the importance of providing said information this study sought to predict which potential donors are likely to become asystolic within a maximum of 240 minutes.

**Materials and Methods**

We sought to develop and validate a tool to predict probabilities of asystole occurring following WLST in potential Maastricht category 3 DCD donors [14].

The study was carried out in two stages.

**Stage 1. Pilot study**

To confirm which variables are routinely measured in critical care units as part of standard care following WLST the APS team (Broderick et al) carried out a multi centre audit, within 15 Intensive Care Units in the South West region of the UK, of 50 potential DCD donors over 6 months in 2010. A draft prediction tool was produced for this purpose.

The pilot data was assessed through review of findings and team discussion to determine which of the measured variables appeared to be significant in predicting time to asystole. Agreed initial variables are listed in Figure 1. These variables were then used as a start point for a literature review, the aim of which was to identify evidence related to those variables significant in predicting time to death.

Four studies were identified which met this aim with main findings being that respiratory function [15-18], coma score [15-18], cause of death [16, 17], inotropic support [15, 17], absent cough reflex [17, 18] and absent gag reflex [15, 16, 18] all have some significance in predicting time to death.

With the exception of absent cough/gag reflex, empirical work has reached no agreement on clinically significant variables. This lack of agreement undermines the clinical use of the tools reported [15-19].

The evidence from the reviewed studies combined with pilot data was used to develop the final scoring tool where each variable identified in the pilot was allocated a series of potential scores weighted by severity (as indicated from the pilot data and literature review) i.e. Glasgow Coma Scale scores were divided into three groups: GCS 3, GCS 4-7 and GCS 8-15 the weighting assigned was 10, 1 or 0 respectively, with higher scores inferring greater severity. Weighting was assigned through review and discussion of the pilot data and evidence. The scores for each variable were added cumulatively to provide an Asystolic Prediction Score (APS) Total. The scoring tool was then validated against the historical data collected in the pilot stage.

The findings from the pilot indicated that many potential donors received elevated concentrations of oxygen despite having PaO2 readings greater than 10, which is accepted as sufficient in critical care patients, and that the presence of secretions had little influence on the time to asystole. A significant and important finding from the pilot study was that the APS score generated had a validity period, i.e. once completed the score could not be expected to remain valid and predictive for the duration of the donation process due to potential changes in the potential donor’s condition. This had not been considered in previous studies. Therefore to further study the importance of the time of assessment and to gain an understanding of the trajectory of change in the patients clinical condition from time of referral to time of WLST the protocol included the requirement to perform the assessment at two time points.

**Stage 2. Observational prospective cohort study.**

The aim of stage two of the study was to test the developed tool in the clinical field.

Recruitment

Four regional Organ Donation Services Teams (South Central, South Wales, Yorkshire and South West) from the UK, working across 76 hospital sites, agreed to assist with data collection. The aim was for all potential donors who met the inclusion/exclusion criteria (Table 1) over a 12 month period to be assessed using the APS Tool (Figure 2).

A protocol was devised and disseminated with face to face training on how to complete the APS Tool. Written guidelines were attached to each audit tool to assist in accurate completion. The assessment was undertaken at tow time points. Time point one being when the specialist nurse in organ donation (SN-OD) arrives at the referral centre (referred to as APS1), and time point two being one hour prior to WLST (referred to as APS2). The protocol also requested that the clinician in charge of the potential donors care indicate whether they expected asystole to occur within two hours of WLST. This was documented on the APS tool.

**Data collection**

The APS tool was completed by the on call Specialist Nurse in Organ Donation (SN-OD) using non-identifiable patient data. The APS tool records data that is routinely collected as part of usual care, no additional monitoring or testing is required. The APS tool was completed as per the protocol with a total score being gained for each potential donor. It was estimated that the APS took approximately 5 minutes to complete on each occasion. Completed audit tools were returned to the APS team.

**Data analysis**

Data was checked for completeness and validated by two members of the team. Where data was found to be missing the relevant SN-OD was contacted and the information was requested.

The APS total scores were grouped together. Group 1 encompassing all scores between 0-15, Group 2 scores 16-20, Group 3 scores 21-25, Group 4 scores 26-30 and Group 5 scores 31+. For analysis purposes statistical tests were carried out using Spearman’s tests for Correlation and Cox Regression for Survival Analysis with SPSS Ver.19. to determine hazard ratios and survival function with probabilities.

**Results**

**Potential Donor Characteristics**

163 potential donors were audited using the APS tool between October 2010 and October 2011. The final study cohort comprised 134 potential donors (29 potential donors had incomplete data sets and were excluded from the analysis). Potential donor demographic characteristics are summarised in Table 2.

74 potential donors (55.2%) became asystolic within 180 minutes of WLST and 59 (45%) potential donors did not become asystolic beyond this time.

Median potential donor age was 59 years (range 20 -78)

The majority of potential donor’s cause of death was neurological: Hypoxic Brain Injury (HBI) 39.6% and Intra Cranial Haemorrhage (ICH) 44.8%

Time to asystole was recorded in minutes with median time to asystole being 85 minutes (range 4 - 8921).

128 potential donors were extubated; of the six who were not extubated three became asystolic within 180 minutes. 39 potential donors required vasoactive medication to support blood pressure prior to WLST and 28 (74%) of these became asystolic within 180 minutes of discontinuing the vasoactive medications at WLST.

Median time to asystole varied significantly amongst the 5 groups for both the APS1 and APS2 assessments. The median time to asystole reduced as APS score increased in all cases (Table 3).

Analysis of changes in APS score by potential donor demonstrated that overall 30% of potential donors changed APS group between APS1 and APS2 with significant movement observed in all groups (Figure 3).

Spearman’s correlation results showed no significant association between cause of death and length of time to asystole following WLST or between age and time to asystole.

Hazard ratios were calculated for each group at time points APS1 and APS2. The ratios increased systematically with each increase in APS score which represents a statistically significant greater risk of asystole occurring with each five point increase in APS score (Table 4).

The estimated survival function of each group related to APS1 (Figure 4) and APS 2 (Figure 5) assessments produced using a Cox regression analysis, demonstrated statistically significant differences in the probabilities of asystole occurring at 30, 60, 120, 180 and 240 minutes following WLST (p<0.001), except in APS1 Group 4 where small numbers led to difficulties in interpretation but on balance the result was felt to be clinically significant in that it was in keeping with the statistically significant results observed in all other groups.

**Probability of Asystole by Group**

Cumulative survival function estimates for each group were used to generate probabilities of asystole occurring within defined time points dependent on the calculated APS score (Table 5).

The likelihood of asystole occuring increases significantly as APS score increases in both APS1 and APS2 assessments. The APS2 score, carried out closer to WLST, has a greater predictive value in determining the probability of asystole occurring following WLST as demonstrated by the higher probabilities of asystole, as shown in Table 3.

There is a difference in the accuracy of APS1 in predicting which donors will become asystolic when compared to APS2, as indicated by the probabilities of death occurring.

APS1 scores were carried out a median time of 519 minutes (120 - 2044 minutes) prior to WLST which has greatly affected its predictive ability. We believe that changes in the clinical condition of the potential donors could have been significant over such long timeframes. APS2 scores were requested to be carried out 60 minutes prior to WLST, scores were completed in a median time of 55.5 minutes (0-298 minutes) prior to WLST.

Potential donors with an APS total score greater than 30 all died within 180 minutes of WLST.

 **Discussion**

We have demonstrated that through the collection of standard recorded data and completion of the APS scoring tool using this information it is possible to provide probabilities for asystole occurring in potential DCD donors. The tool provides a statistically sound method of categorising potential donors by group and differentiating between these APS groups to offer a clear rationale for decision making during end of life care.

The survival function graphs clearly demonstrate that 80% of potential donors who scored greater than 30 died within 30 minutes of WLST, which could be of great interest to multi organ retrieval teams in understanding which organs are likely to be suitable for transplantation following retrieval.

The likelihood of significant changes in the potential donor’s condition is greatly decreased over such a small timeframe which will clearly increase and improve the accuracy of the score. We have suggested a method for overcoming this disparity.

We have demonstrated through our own data collection that clinical changes occur in the hours preceding WLST, with both improvements and deterioration of clinical findings, and therefore using data collected shortly prior to WLST to create a model to predict asystole would be difficult to interpret in a clinical environment. Recent studies by Yee [18], de Groot [20], Rabinstein [21], Wind [4] and Davila [22] all collected data at a single time point, shortly prior to WLST yet it has been clearly demonstrated that in 30% of the potential donors in this study the score calculated at initial referral was significantly different to the score calculated one hour prior to WLST. This is a very important finding which should be given serious consideration when assessing validity of tools to predict asystole.

The ultimate purpose of any tool to predict donor’s potential to become asystolic within a defined timeframe is to determine suitability and eligibility as a potential DCD donor. Therefore it follows that this assessment would be required at initial assessment and hence should be valid at this time point, prior to undergoing the process of donation facilitation which may take up to 20 hours. We strongly suggest that any further work on prediction scoring must be carried out using data collected at earlier timeframes.

We propose a protocol which is based on determining the planned time of WLST, agreed with cooperation between the ICU staff, the SN-OD, the family, the retrieval team +/- the transplant team. Using such an approach the APS1 score could be completed 6 hours prior to this planned WLST and the information relayed to the family and this extended clinical team for further decision making, therefore allowing time for organ acceptance and for the retrieval team to travel to the donating hospital site.

The use of such a tool could have a significant impact on organ donation practice in the UK. Accurate probabilities of when asystole is likely to occur could be shared with family members of potential donors reducing the uncertainty that they experience during the DCD process and could also assist clinicians in managing the family’s expectations and contribute to their understanding of the complex nature of end of life care and the DCD process.

**Considerations for Future Studies**

Cause of death currently recorded by NHSBT does not accurately reflect the mechanism of injury leading to death nor does it provide specific definitions in all cases. We felt that this affected the ability to fully explore cause of death as a predictor as has been shown in the literature. Hypoxic Brain Injury (39.6%) and Intra-cranial haemorrhage (44.8%) combined accounted for 84.4% of the cause of death in potential donors in this study, yet the two terms cover a multitude of potential mechanisms of injury and degrees of severity. Obtaining greater detail on the mechanism of injury may allow a more detailed analysis to take place and potentially improve the accuracy and predictive value of individual scores. Information on the gender of the donors was not collected and this should be included in future studies, however there is no available evidence to suggest that gender is linked to time to asystole following WLST.

GCS scores were obtained following a SN-OD’s individual assessment where possible and appropriate and where this was not possible scores were taken from medical records or charts. Of note, and an important issue for practice, is that often GCS scores were noted to have been measured when patients were on sedation, GCS scores of 3/15 were also seen to be recorded when patients were ventilated or when motor response from stimulation within the cranial nerve distribution was witnessed by SN-OD’s. The GCS score was measured in all patients included in our audit regardless of their condition which would not have been appropriate in all cases.

**Conclusion**

The tool offers a potential solution to the difficult issue of human resource allocation. With increasing numbers of potential donor referrals the issue of prioritising attendance at potential donors will become an increasing issue with limited numbers of specialist nurses – organ donation available to attend. Assessing which potential donors have the greatest probability of reaching asystole and therefore lead to successful transplants could be determined using the tool thereby assisting the difficult task of prioritising with a clear rationale for decision making. The tool could also assist transplant teams in understanding which donors are likely to result in a successful retrieval.

The tool also has potential implications for general end of life care regardless of potential for donation. As shared decision making continues to be advocated across healthcare sectors tools which can inform the process are likely to have great value.

The value of GCS score has been the subject of debate in critical care areas; we have found that this information may be a poor predictor value due to the subjective nature of the assessment and we suggest that future work in predictive tools should test an alternative tool for assessment of coma scores. The FOUR coma score has been under development to assess patients in ICU. We plan to explore the use of this tool in future work. Similar work in predicting time to asystole following WLST by Yee [18], de Groot [20], Rabinstein [21] and Davila [22] have found absent cough and absent corneal reflexes to be significant in predicting death within 60 minutes of WLST and therefore these variables will be considered for inclusion in further work.

The APS1 score is less accurate in predicting probability of asystole than the APS2 score (See Table 5). As discussed this is due to the significant difference in times of assessment compared to WLST. Simple methods could be employed to improve the accuracy of the APS tool, including overcoming discrepancies in coma scores, exploring with critical care staff and donor families acceptable methods for collection of more detailed data (particularly oxygenation measurement) and most significantly, designating by protocol the time at which the APS1 score is carried out prior to WLST. This action will improve the predictive accuracy of the APS 1 score to enable the tool to be used clinically in a model to determine true potential DCD donors.

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**Figures**

Fig 1: Initial Variables Assessed in the Development and Design of the APS Scoring Tool



Fig. 2: Asystole Prediction Scoring Tool



Fig. 3: Movement between groups at APS1 and APS2 demonstrating the importance of protocol led assessment of time to asystole



Fig. 4: APS 1 Survival function at 180 minutes. Demonstrating the cumulative survival at varying time points by first assessment group.



Fig. 5: APS 2 Survival function at 180 minutes. Demonstrating the cumulative survival at varying time points by second assessment group.



**Tables**

Table 1. Inclusion and Exclusion Criteria

|  |  |
| --- | --- |
| **Inclusion criteria**  | **Exclusion Criteria** |
| All patients referred as potential DCD donors to the South West, South Central, South Wales and Yorkshire Organ Donation Services Teams between October 2010 and October 2011. | Potential donors under the age of 16 years.Brain Stem Dead potential donorsPatients not intubated.  |

Table 2. Potential Donor Demographics

|  |  |
| --- | --- |
| N | 134 |
| Age (yr) Median (range) | 59 (20-78) |
| Asystolic within 180 mins of WLST | 74 (55.2%) |
| Time to asystole (mins) Median (range) | 85 (4-8921) |
| Primary Cause of Death |  |
| * Intra Cranial Haemorrhage
 | 60 (44.8%) |
| * Hypoxic Brain Injury
 | 53 (39.6%) |
| * CVE
 | 8 (6.0%) |
| * Traumatic Head Injury
 | 6 (4.5%) |
| * Respiratory Failure
 | 2(1.5%) |
| * Multi Organ Failure
 | 2 (1.5%) |
| * Cardiac Failure
 | 1 (0.7%) |
| * Brain Tumour
 | 1 (0.7%) |
| * Alcoholic Liver Disease
 | 1 (0.7%) |
| Extubated at WLST | 128 (95.5%)  |
| Vasoactive medication discontinued at WLST | 39 (29.1%)  |
| Time between APS1 score and WLST (minutes) Median (range) | 519 (120 – 2044) |
| Time between APS2 score and WLST (minutes) Median (range) | 55.5 (0 – 298) |

Table 3. Median Time to Asystole by Group for APS1 and APS2 Scores

|  |  |
| --- | --- |
| Median Time to Asystole (minutes) | APS1 Groups |
| 1 | 2 | 3 | 4 | 5 |
| 1300 | 410 | 43 | 30 | 18 |
| Median Time to Asystole (minutes) | APS2 Groups |
| 1 | 2 | 3 | 4 | 5 |
| 1572 | 475 | 43.5 | 22 | 16.5 |

Table 4. APS1 & APS2 Frequencies and hazard ratios at 180 minutes post WLST

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| APS1 Score | Frequency | Asystole within 180 mins of WLST | Exp(B) Hazard ratio | Significance |
| 0-15 | 41 | 12 (29.2%) | .099 | .000 |
| 16-20 | 25 | 10 (40 %) | .167 | .000 |
| 21-25 | 33 | 18 (54.5%) | .251 | .000 |
| 26-30 | 11 | 10 (90.9%) | .540 | .112 |
| 30+ | 24 |  24 (100%) |  | .000 |
| Total | 134 |  |  |  |
| APS2 Score | Frequency | Asystole within 180 mins of WLST | Exp(B) Hazard ratio | Significance |
| 0-15 | 32 | 4 (12.5%) | .039 | .000 |
| 16-20 | 24 | 8 (33.3%) | .104 | .000 |
| 21-25 | 38 | 24 (63.1%) | .252 | .000 |
| 26-30 | 12 | 9 (75%) | .380 | .016 |
| 30+ | 28 | 28 (100%) |  | .000 |
| Total | 134 |  |  |  |

Table 5. Estimated probabilities of asystole occurring at defined time points post WLST.

|  |
| --- |
| Probability Estimates of Asystole Occurring at Timepoints following WLST |
| APS1 | WLST + 30mins | WLST + 60mins | WLST + 120mins | WLST + 180mins | WLST + 240mins |
| 0-15 | 10% | 14.9% | 24% | 28.6% | 29.2% |
| 16-20 | 36.2 % | 41.2% | 42.8% | 43.6% | 47% |
| 21-25 | 41.7% | 51.3% | 56.5% | 58.1% | 60.2% |
| 26-30 | 59.2% | 61.9% | 74.8% | 84.3% | 85.7% |
| 30+ | 18.2% | 88.7% | 95.8% | 96.9% | 97.7% |
|  |
| Probability Estimates of Asystole Occurring at Timepoints following WLST |
| APS2 | WLST + 30mins | WLST + 60mins | WLST + 120mins | WLST + 180mins | WLST + 240mins |
| 0-15 | 0% | 0% | 12.5% | 15.5% | 15.5% |
| 16-20 | 25.3% | 30.5% | 31.1% | 35.6% | 42.3% |
| 21-25 | 41.7% | 52.4% | 61.4% | 65.2% | 66% |
| 26-30 | 62.6% | 66% | 73.7% | 79.4% | 80.5% |
| 30+ | 81.4% | 92.5% | 98% | 98.8% | 99.1% |