Can the Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS) be used to accurately report clinic total reproductive potential (TRP)?

Judy E. Stern, Ph.D.,[a] Timothy N. Hickman, M.D.,[b] Donna Kinzer, M.S.,[c] Alan S. Penzias, M.D.,[c] G. David Ball, Ph.D.,[d] and William E. Gibbons, M.D.[e]

[a] Department of Obstetrics and Gynecology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire; [b] Houston IVF, Houston, Texas; [c] Boston IVF, Waltham, Massachusetts; [d] Seattle Reproductive Medicine, Seattle, Washington; and [e] Department of Obstetrics and Gynecology, Baylor College of Medicine, Houston, Texas

Objective: To assess whether total reproductive potential (TRP), the chance of a live birth from each fresh cycle (fresh cycle plus frozen transfers), could be calculated from the national Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS) database and whether information not available in SART CORS resulted in significant changes to the TRP calculation.
Design: Retrospective study using SART CORS and clinic data.
Setting: Three assisted reproductive technology clinics.
Patient(s): Women undergoing ART.
Intervention(s): None.
Main Outcome Measure(s): Two- and three-year TRPs for 2005 and 2006 were calculated according to patient age at cycle start by linking fresh to frozen cycles up to first live birth. Clinic records were used to adjust for (remove) frozen cycles that used more than one fresh cycle as a source of embryos and for any embryos donated to other patients or research or shipped to another facility before a live birth.
Result(s): TRP was higher than fresh per-cycle rates for most ages at all clinics, although accuracy was compromised when there were fewer than 20 cycles per category. Two- and 3-year TRPs differed in only 2 of 24 calculations. Adjusted TRPs differed less than three percentage points from unadjusted TRPs when volume was sufficient.
Conclusion(s): Clinic TRP can be calculated from SART CORS. Data suggest that calculations of clinic TRP from the national dataset would be meaningful. (Fertil Steril® 2012;97:886–9. ©2012 by American Society for Reproductive Medicine.)
Key Words: Total reproductive potential, cumulative delivery rate, ART outcome, SART database

Assisted reproductive technology (ART) outcomes in the U.S. are reported annually to both the Society for Assisted Reproductive Technology (SART) and the Centers for Disease Control and Prevention (CDC) on a live birth per treatment cycle per year basis and not a live birth per woman basis. Although outcome per cycle rates are important, this reporting mechanism has resulted in an emphasis on the initial fresh embryo transfer that has had some negative consequences. One such consequence is that some clinics have sought to maintain and sustain high "competitive" fresh cycle pregnancy rates by increasing the number of embryos transfered, which has, in turn, led to unwanted excess multiple pregnancies (1). These multiple pregnancies have had enormous negative health consequences and economic impact (2).

The desire to reduce multiple pregnancy after IVF has raised interest in finding a way to report national data from a single fresh cycle to include the contribution of subsequent frozen embryo transfers derived from it, a value called the total reproductive potential (TRP) (3, 4). Studies of TRP have also been suggested as a way to increase single-embryo transfer (SET)

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Reprint requests: Judy E. Stern, Ph.D., Department of Ob/Gyn, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756 (E-mail: judy.stern@dartmouth.edu).

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(5). The calculation of TRP is similar to, but somewhat different from, the calculation for cumulative delivery rate, which has also been studied recently (6, 7). Cumulative delivery includes the outcome of multiple fresh cycles and may include both fresh and frozen cycles to the point of live birth. TRP is specific to results from a single fresh cycle.

The present pilot study was undertaken to determine if sufficient information exists in the national SART Clinic Outcome Reporting System (SART CORS) database to calculate TRP on a clinic-by-clinic basis and thus provide a new way to report clinic results. Our goals were to: 1) determine whether it is possible to calculate TRP using SART CORS data only; 2) to calculate an adjusted TRP using information of importance that is currently missing from SART CORS; and 3) to determine how far the adjusted rate is from the unadjusted rate, thus evaluating whether the TRP calculation from SART CORS would be acceptable for national reporting purposes.

MATERIALS AND METHODS

Three clinics participated in this retrospective study using clinic data from 2005–2008. Clinics included a small rural clinic (clinic A) a midsized urban clinic (clinic B), and a large urban clinic (clinic C). Each clinic downloaded their own clinic data from SART CORS and used those data to calculate TRP on the basis of patient age at cycle start. Each clinic did their own calculations and obtained Institutional Review Board approval for the study at their own location.

SART CORS was queried using the Advanced Report Menu under which the All Fields Export function was chosen. Each clinic that reports to SART CORS can use these functions to export their own clinic data for quality assurance activities and research. Downloaded data contain the patient identifiers, name, clinic-specific record number, and date of birth so that repeated cycles can be matched for each patient.

Each participating clinic downloaded their data for fresh autologous cycles initiated in either 2005 or 2006. Banking cycles (no planned embryo transfer) and gestational carrier cycles were excluded. SART CORS was then queried to obtain all frozen autologous cycles for the years 2005–2007 to use in calculations of 2005 TRP, and for 2006–2008 to use in calculations of 2006 TRP. An unadjusted TRP was calculated for fresh cycles from 2005 or 2006 by linking fresh to frozen cycles for each patient over the 2- or 3-year period. For each initiated cycle, the fresh plus any frozen cycles were included up to and including either the first live birth or the next fresh cycle (Fig. 1). Data were calculated for each age group: <35 years, 35–37 years, 38–40 years, and >40 years. Calculations used the fresh cycle as the denominator, so the rate for fresh cycles in which live birth was achieved without any frozen cycles included was the per-cycle rate originally reported by that clinic as the fresh autologous rate.

Each clinic reviewed medical records and added additional information, not currently in SART CORS, to use in calculation of an "adjusted TRP." Cycles were completely removed from the calculation if within the 2- or 3-year time frame and before a live birth, embryos were shipped offsite, donated to research or another couple, or discarded or if embryos from two or more retrievals were thawed for a frozen transfer.

FIGURE 1

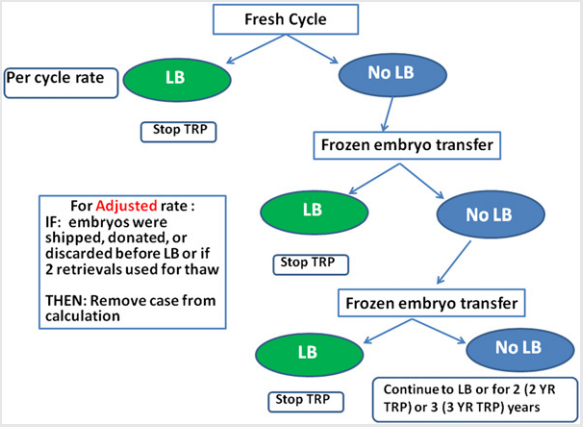

Diagram showing methods for calculating unadjusted and adjusted total reproductive potential (TRP) rates. Fresh plus frozen cycles are included in TRP up to either live birth (LB) or a new fresh cycle.

Stern. Calculation of TRP at three clinics. Fertil Steril 2012.

RESULTS

Unadjusted and adjusted TRP are presented for clinics A, B, and C in Table 1. Live birth rates per cycle are shown for comparison. The per-cycle rates differ slightly from rates reported on www.sart.org because gestational carrier cycles were not included. Unadjusted 2- and 3-year TRP differed in only 2 of 24 cases. In one case (clinic C, <35-year-olds, 2005), this difference was 0.1 percentage points, in the other (clinic A, 35–37-year-olds, 2006) it was 3.6 percentage points.

Clinics B and C had adjusted TRP rates that differed from unadjusted TRP rates by no more than 2.6 percentage points. Clinic A, with lower volumes, had wider swings in rates, with several adjusted rates being lower than unadjusted rates owing to the change in denominator when cycles were removed. In one case, that of the 2005 >40-year-old group (n = 7), the difference was 21.4 percentage points, because three of the seven cycles were removed in the adjusted rate. At clinics A and C, most frozen embryos were transfered, discarded, donated, or shipped within the 3-year window. At clinic B, there were some patients who had no live birth and still had embryos in storage at 3 years. Had these been removed from calculation, the adjusted calculation for clinic B in women <35 years old would have differed by 10% from the unadjusted rate.

DISCUSSION

This study is the first attempt to use a national database to calculate and define success of ART with the use of TRP rather than per-cycle rates. We have shown that TRP can be calculated from the SART CORS database and that, at the three clinics studied, there is a marked decline in TRP with age

TABLE 1

Per-cycle and total reproductive potential (TRP) rates at three SART clinics.

				2-y TRP (%)			3-y TRP (%)		
Age group (y)	Year of fresh cycle	n[a]	Per cycle (%)[a]	Unadjusted	Adjusted	A − U	Unadjusted	Adjusted	A − U
Clinic A									
<35	2005	54	31.5	37.0	38.5	1.5	37.0	38.5	1.5
	2006	56	42.9	46.4	48.1	1.7	46.4	48.1	1.7
35–37	2005	23	26.1	29.2	33.3	4.1	29.2	33.3	4.1
	2006	28	35.7	39.3	38.4	−0.9	42.9[b]	46.1	3.2
38–40	2005	24	12.5	16.7	19.0	2.3	16.7	19.0	2.3
	2006	25	40.0	40.0	37.5	−2.5	40.0	37.5	−2.5
>40	2005	7	14.3	28.6	50.0	21.4	28.6	50.0	21.4
	2006	21	14.3	14.3	16.7	2.4	14.3	16.7	2.4
Clinic B									
<35	2005	119	47.9	48.7	49.2	0.5	48.7	49.2	0.5
	2006	132	50.8	56.1	57.8	2.6	56.1	57.8	2.6
35–37	2005	62	38.7	40.3	41.0	0.7	40.3	41.0	0.7
	2006	76	47.4	51.3	52.0	0.7	51.3	52.0	0.7
38–40	2005	39	38.5	38.5	38.5	0	38.5	38.5	0
	2006	42	28.6	33.3	33.3	0	33.3	33.3	0
>40	2005	37	13.5	13.5	13.5	0	13.5	13.5	0
	2006	31	12.9	12.9	12.9	0	12.9	12.9	0
Clinic C									
<35	2005	868	32.5	36.2	36.2	0	36.3[c]	36.3	0
	2006	701	37.1	40.2	41.4	1.2	40.2	41.4	1.2
35–37	2005	586	25.4	26.1	27.0	0.9	26.1	27.0	0.9
	2006	500	29.2	32.0	32.6	0.6	32.0	32.6	0.6
38–40	2005	548	16.6	17.7	18.2	0.5	17.7	18.2	0.5
	2006	492	19.7	20.5	20.9	0.4	20.5	20.9	0.4
>40	2005	385	10.6	10.9	11.0	0.1	10.9	11.0	0.1
	2006	313	9.0	9.0	9.0	0	9.0	9.0	0

Note: A − U = adjusted minus unadjusted.
[a] Number of cycles and per-cycle rates may differ slightly from values at www.sart.org because gestational carrier cycles are not included here.
[b] Differed from 2-year TRP by 3.6 percentage points.
[c] Differed from 2-year TRP by 0.1 percentage point.

Stern. Calculation of TRP at three clinics. Fertil Steril 2012.

and little difference between a calculation of 2-year and 3-year TRP. We have further shown that an adjusted TRP calculation that includes information not reported to SART CORS, but of potential importance to TRP, varies somewhat by clinic practice but differs by no more than 3.0 percentage points from unadjusted values as long as cycle number is adequate. The study suggests that valid TRP calculations can be generated from SART CORS data and that the per-clinic-cycle summary reports on the national reporting website could include a TRP calculation in addition to a per-cycle rate.

TRP, defined as the live birth rate per patient cycle including both fresh and frozen cycles up to first live birth, has long been proposed as an alternate and perhaps better way to report the success rates for ART than per-cycle reporting (3, 4). National reporting of per-cycle rates has been criticized as privileging those clinics that transfer excessive numbers of embryos over those that transfer fewer (8). Given the competition between clinics for ever higher success rates, this has the potential to increase the rate of multiple pregnancy, as shown in a report by a SART research committee writing group, whereby clinics with lower implantation rates transferred more embryos to sustain their fresh pregnancy rate at a cost of higher multiple pregnancy rates (1). Several studies in both the U.S. and Europe have demonstrated that TRP can offer a better ongoing measure of ART success (5, 9–11).

TRP is different from cumulative delivery rate, which has gained popularity recently (6, 7, 12–16). Cumulative delivery is the live birth rate per patient from a group of cycles and includes multiple fresh and frozen cycles resulting in rates of live birth per woman. By contrast, for TRP the denominator is a single fresh cycle. Cumulative rates have been shown to decline with age (6, 7, 12). TRP rates in the present study also declined with age. Cumulative delivery rate is a good way to report results, but it has the disadvantage compared with TRP of not exerting downward pressure on the number transferred.

The value of 2-year versus 3-year TRP has been debated; the present study showed little difference between the two. There has also been debate about whether some cycles should be excluded from calculation (i.e., adjusted out). For adjusted TRP, we removed cycles from calculation if they included embryos thawed from more than one cycle, or if embryos were shipped or donated before a live birth. We could have opted to exclude those cycles even if a live birth occurred, or we could have continued to include one or more of those categories. Using this stricter method in conjunction with SART CORS data, we found that when cycle numbers were sufficient, there was little difference between adjusted and unadjusted rates. This strengthens the argument that TRP can be calculated from SART CORS. Calculating TRP would require

waiting for several years of data to be accumulated in SART CORS. Reported SART information is already more than a full year behind the current time, and 2-year TRP reported for a particular year would have to be more than 2 years behind the current time frame. Because clinic practice and success rate can change over time, there may be problems with the accuracy of this measure. However, reporting the rate of elective SET and the percentage of singleton deliveries can continue to be used along with reporting of TRP, and these will continue to show data for the most current reporting year.

Differences in clinic practice can affect both the accuracy of a TRP calculation and its usefulness. Of the three clinics analyzed for this pilot study, two (clinics A and B) made regular use of cryopreservation and frozen embryo transfer. The third (clinic C) often performed repeated fresh cycles before a frozen cycle with thawing of embryos cryopreserved from multiple cycles. Clinic B also had several patients with no live birth who had not returned for a frozen cycle even after 3 years. Such things affect TRP rate. Stage of embryo freezing may also affect TRP. Several earlier studies of TRP used pronuclear-stage freezing (9, 10); however, many U.S. clinics freeze at cleavage or blastocyst stage.

As with per-cycle rates, small clinic size can result in loss of accuracy in TRP calculations. Accuracy of the TRP calculation in the present study was clearly influenced by number of cycles (as in clinic A). Similar problems might result for other small clinics. One alternative for small programs could be to collate results from more than 1 year to allow data on a minimal number of cycles, e.g., 50 per grouping. The longer time would not penalize these smaller clinics and would smooth out variation in patient numbers.

This study has several limitations. Although three very different clinics were used, these clinics are just a small sample of the many clinics that perform ART and therefore may not capture all of the variations and permutations that could arise should this calculation be used nationally. In addition, the information gathered for SART CORS has changed over time, e.g., the inclusion of cycle from which frozen embryos originated is now in SART CORS but could not be directly included in the present calculations because that field was not available in the years studied. Its addition will help with future calculations of TRP.

We have demonstrated that TRP can be calculated from SART CORS and that, in most cases, this calculation differs little from a calculation that includes additional information from the clinic records. To be used nationally, the method for calculating TRP from SART CORS data will have to be agreed on through discussion with SART member clinics. Nevertheless, national reporting of TRP might lead to greater use of frozen embryo transfer and result in a lower number of embryos transferred in fresh cycles and fewer multiple pregnancies with their attendant costs and complications.

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