

Background

- When a surgeon implements changes in an operation to improve outcome, it can be evaluated by:
 - Prospectively randomized study of different methods
 - Retrospective review with comparison to accepted published standards, case controls, or historical data
- Previous self-assessment tools have relied on comparing series of cases retrospectively or by retrospective video review by self or an expert; however, these may not account for changes in technology over time
- The objective of this study is to determine a way of assessing surgical technique improvement in an ongoing, prospective manner
- Characteristics of procedures best suited for proposed self-analysis:
 - Easily definable and reproducible** intervention or procedure (eg, Total thyroidectomy (TT))
 - Easily definable outcome or complication** (eg, immediate post-TT PTH level) that are **impacted by the action of the operator** (vs eg, co-morbidities not under the control of the operator) and measurable shortly post-operatively
 - Established rate of outcome or complication** based on literature and/or personal series (commonly reported rates of hypoparathyroidism are between 20-30%), as references
 - Easily definable and reproducible implemented changes** in medication, technique, instrumentation or visualization that are expected to significantly alter outcome
 - Improving outcome or reducing complications** with tangible implications such as better quality of life, less medications use, and shortened length of stay
- Potential problem: Unaccounted for variables and co-morbidities that might affect outcome and rate of complication

Rationale and Methods

To calculate the numbers needed in a series used for comparison, let:

p = probability of success

$\hat{p}$ = estimate for p

q = (1 – p) = probability of failure

z = reliability coefficient for the normal approximation (z = 1.96 for 95% confidence interval)

Then the 95% confidence interval for a proportion is given by:

$$\hat{p} \pm z \sqrt{\frac{pq}{n}}$$

Self-Assessment of Parathyroid Preservation in Total Thyroidectomy

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Rationale and Methods, continued

Suppose we wish to estimate n = the sample size required to reach a certain precision in our estimate, then:

$$\text{Error} = E = z \sqrt{\frac{pq}{n}}$$

And we can solve for n to obtain: $n = \frac{z^2 pq}{E^2}$

Therefore, **sample size** = n is a **function of** the **confidence level** you desire, the **probability of success/failure**, and the **amount of error** you are willing to accept in your estimate.

So for an error of 5%, $E = 0.05$ and $p = 0.8$, $q = 0.2$, the n using $z = 1.96$ would be **246**.

Changing only the probability of success, $p = 0.5$, $q = 0.5$ yields the largest n of **384**, whereas with $p = 0.95$, $q = 0.05$ yields the n of **69**.

In a **series without complications**, let:

n = number of cases, the

p = predicted probability of success (assumed same in each procedure)

Then P = probability of occurrence is p to the power of n , or

$P = p^n$ which in Excel, is **POWER(p, n)**

If $P < 0.05$ is used as a threshold of “significant” difference in observed vs. predicted, then n is the number of consecutive cases unlikely to happen by chance and therefore achieves a significant improvement over the predicted success rate when solved for $p^n < 0.05$

For example if the historical or predicted success rate is **80%**, then $0.8^n < 0.05$ is achieved when $n \geq 14$ since $0.8^{14} = 0.044$

In a **series with complications**, the probability of occurrence = P is not simply $p^r \times q^{n-r}$ because of the **combinations** of where the complications appear in the series.

It is expressed as $\binom{n}{r} = \frac{n!}{r!(n-r)!}$ = **number of combinations** of r successes in n trials, where

r = number of successes out of n trials

Leading to a binomial formula provides an estimate of the probability of a certain number of success

$$P(X = r) = \binom{n}{r} p^r q^{n-r} = \frac{n!}{r!(n-r)!} p^r q^{n-r}$$

Where X = binomial distribution function

In Excel, **COMBIN(n, r)** = number of possible combinations, which are very large numbers in large series with complications, The actual probability of occurrence is then $p^r \times q^{n-r} \times \text{COMBIN}(n, r)$

So for **1 failure** (notice prior formula used successes): $\binom{n}{1} 0.8^{n-1} q^1 < 0.05$, and this occurs when $n \geq 21$ (ie, 20 successes, 1 failure)

If a surgeon is in the midst of a series to improve success rate above 80%, with **one complication so far**, then the number of total cases needed to achieve $P < 0.05$ assuming only one complication occurs in the series would be $n \geq 21$ since $0.8^{20} \times 0.2^1 \times 21 \text{ combinations} = 0.048$, or at least **20 successes with the one failure**.

For **2 failures**: $\binom{n}{2} 0.8^{n-2} q^2 < 0.05$, and this occurs when $n \geq 28$ (i.e., **at least 26 successes with only 2 failures**)

To use these formulas to deduce how many total or successful cases are needed to reach $P < 0.05$ for a given number of complications, that the target level of success is exceeded, tables can be constructed:

Probability of Success									
Failures	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
0	2	2	3	4	5	6	9	14	29
1	3	4	5	6	8	10	15	21	44
2	4	6	7	8	10	13	18	28	57
3	6	7	8	10	13	16	22	34	70
4	7	8	10	12	15	19	26	40	81
5	8	10	12	14	17	22	30	46	93
6	9	11	13	16	20	25	34	52	104
7	11	13	15	19	22	28	38	57	116
8	12	14	16	20	24	31	41	63	127
9	13	15	18	21	26	33	45	68	137
10	14	17	20	23	28	36	49	73	148

Table 1: The number of total cases needed to reach $P < 0.05$ for a given number of complications and a given probability of success

The **smaller the series**, the **higher the success rate one would have to have** to show $P < 0.05$. With the target of being better than a 20% true complication rate,

- At 5 complications **of 46 total**, the raw complication rate is **11%**
- At **15 and 100** respectively, it would be **15%**
- At **30 and 176** respectively, it would be **17%**

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Results

- The tables can be constructed to show the number of successes (e.g. from 0 to 30) vs. target failure rate (e.g. from 0.2 to 0.5) with the number of failures or total cases at each intersection being that which will produce a probability of < 0.05 that the results are worse than the target failure rate.
- The numbers of success/failure can also be substituted for each other on the prior table to show how many total or failed cases are needed to reach $P < 0.05$ for a given number of successes, that the target level of failure is exceeded.
- In this case, if the target is **significantly worse than 20% complication rate**,
 - at **5 successes and 46 total**, the raw complication rate would be **89%**
 - at **15 and 100** respectively, it would be **85%**
 - at **30 and 176** respectively, it would be **83%**.
- The surgeon would have to do better in raw numbers in a small series than the goal to be assured that they are statistically doing so
- The surgeon would also have to do worse in raw numbers to show that they are doing statistically worse than the goal.

Conclusions

- A surgeon seeking to **improve upon their rate of hypoparathyroidism** can use this **ongoing assessment** to determine if a change in technique is effective by monitoring whether consecutive favorable cases approaches the threshold of low probability that they set
- This prospective self-assessment tool can be used by **young surgeons without large case numbers**, and **experienced surgeons** who want to analyze complication rates with **changes in technique**
- The imposition of this self-assessment tool by itself may result in improvement as the surgeon tries to **outdo themselves with each successive case**

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