

Is the rate of frozen section discordance affected by subspecialty sign out? A quality improvement study

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Abstract

Background: Monitoring frozen section (FS) and final permanent section (PS) correlation is a valuable quality assurance metric in surgical pathology. The discordant FSs, at our institution, are categorized as minor if there is little or no perceived or actual clinical significance and major if there is major or potentially major clinical significance, which is determined by the final sign out pathologist. We sought to determine if the subspecialty sign out (SSSO) model, which was instituted in July of 2015, has adversely impacted our discordance rate.

Methods: We retrospectively reviewed the discordance rates (DRs) before (January 2012-June 2015) and after (July 2015-2017) SSSO. The monthly intraoperative consultation FS and PS correlation data were analyzed from January 2012 to January 2018. The DRs were compared for minor, major and combined disagreements (minor + major) before and after SSSO.

Results: There were 7,045 total frozen sections with 2,989 after SSSO and 4,056 prior to SSSO, of which 139 had minor disagreements (74 prior to SSSO and 65 after SSSO) and 42 had major disagreements (26 prior to SSSO and 16 after SSSO). The average combined DRs per month; pre and post SSSO were 2.17 and 3.0, respectively. The difference was statistically significant for the minor ($p=0.005$), not statistically significant for the major ($p=1$) and statistically significant for the combined ($p=0.014$) disagreements.

Conclusion: Our data shows that SSSO appears to increase FS discordance rates (minor and combined disagreements). This suggests that when adopting a SSSO model, maintaining competency with a wide array of specimens seen on a general intraoperative consultation service may be challenging and warrants careful monitoring of frozen and permanent section discrepancy rates.

Background

Monitoring frozen section (FS) and final permanent section (PS) correlation is a valuable quality assurance metric to utilize in a surgical pathology department. It has been suggested that monitoring frozen section discordant rate can decrease an institution's discrepancy rate over time. Several studies have reported a combined discrepancy rate of approximately 2% for frozen section discordance [1-8]. The Association of Directors of Anatomic and Surgical Pathology (ADASP) have a 3% accuracy threshold for major disagreements [9]. Lowering discrepancy rates and discordant FS and PS results is important because this may alter clinical management and possibly outcome. In July 2015, our department implemented full subspecialty sign-out (SSSO) while maintaining general sign-out of frozen sections. The discordant FSs, at our institution, are categorized as minor if there is little or no perceived or actual clinical significance and major if there is major or potentially major clinical significance, which is determined by the final sign-out pathologist. We sought to determine if the SSSO model has adversely impacted our FS and PS discordance rate.

Design

Since this was an intradepartmental quality improvement study, institutional review board approval was waived. We routinely monitor the intraoperative frozen and permanent section correlation on a monthly basis as part of our routine quality assurance monitoring parameters. The discordant cases are classified as minor (little or no perceived clinical significance) and major (potentially major clinical

significance). We retrospectively evaluated our quality assurance data for the discrepancy rates (DRs) before SSSO (January 2012-June 2015) and after SSSO (July 2015-December 2017) at a single academic institution. The DRs were compared for the minor, major and combined disagreements (minor + major) before and after SSSO using the student's t-test with a p-value of 0.05 or less considered statistically significant (www.medcalc.org).

Results

There were 7,045 total frozen sections performed during the study period of January 2012 to December 2017, of which 4,056 were prior to SSSO and 2,989 post SSSO. There were 139 minor disagreements (74 prior to SSSO and 65 after SSSO) and 42 major disagreements (26 prior to SSSO and 16 after SSSO). The average combined DRs per month; pre- and post- SSSO were 2.17 and 3.0, respectively. There was an increase in minor discrepancies after adopting the SSSO model. The rate of major discrepancies decreased slightly after adopting the

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SSSO. The average combined DRs before and after SSSO were 2.17 and 3.0, respectively. The difference was statistically significant for the minor ($p=0.005$), not statistically significant for the major ($p=1$), and not statistically significant for the combined ($p=0.014$) disagreements (these results are summarized in Tables 1 and 2). The most common types of discrepancies overall were misinterpretations. Amongst the minor discrepancies, misinterpretations and block sampling increased when adopting the SSSO model. There was a large portion of minor discrepancies, both pre and post SSSO, which had not been clearly documented.

Discussion

White and Trotter [1] reported a combined disagreement rate of 3.09 when uncorrected for deferrals. This is slightly higher than our combined disagreements post-SSSO. White and Trotter [1] refer to several studies that found an approximate 2% overall disagreement rate at different institutions throughout the world. An individual institution has potential for improvement in discrepancy rates over time whilst monitoring quality improvement in frozen sections [7].

A recent study from Sams and Wisell [10] retrospectively evaluated 1,042 frozen sections and they found a total of 48 discrepancies (4.6%). A slight majority of their discrepancies involved process errors (54.2%) which included mostly sampling errors while interpretation errors accounted for the remainder (45.8%) and included false negatives/undercalls, false positives/overcalls, and misclassification errors. They also determined that the error rates varied by organ system.

One reason for our increased combined discrepancy rate compared to other studies may be due to the degree of complexity of our surgical cases. Another reason may be due to the fact that most of our institution's discrepancies are a result of an increase in minor discrepancies such as finding atypical cells obscured by frozen section artifact while the permanent section shows atypical cells conclusive for malignancy. Minor discrepancies, by definition, do not have major clinical implications [8]. The data shows that SSSO, at this institution, appears to generally increase minor FS discrepancy rates which are largely attributable to an increase in misinterpretations and block sampling (minor and combined disagreements). Interestingly, there was an almost twofold increase in interpretive errors before and after SSSO (20 versus 39) in the minor discrepancy category. It is unclear if this is because pathologists are focused on only one or two organ systems and have lost competency or feel uncomfortable with other organ systems that commonly undergo frozen section analysis. One could argue that this suggests that when adopting a SSSO model, maintaining competency with a wide array of specimens seen on a general

intraoperative consultation service may be challenging and requires careful monitoring of frozen and permanent section discrepancy rates. However, we believe that the increase in minor discrepancies that may result after implementation of SSSO is a fair trade off given that in some instances SSSO is associated with improved accuracy and reporting and that by definition minor FS discrepancies are clinically insignificant [11-16]. One way to decrease minor discrepancy rates would be to obtain a consult from a subspecialized pathologist on every frozen section or to have a subspecialty frozen section service altogether, however these solutions would not be efficient and would require additional staff to function as intraoperative consultation specialists. Our study also shows that the overall major discrepancy rate has decreased. Although this decrease is not statistically significant, we argue that it is clinically significant.

While subspecializing might theoretically and practically lead to specialized pathologists losing competence in general pathology, it also increases the competency in the pathologist's area of specialty [11-16]. Thus, when performing a frozen section on a difficult case during normal business hours, the frozen section pathologist can consult a specialist in that particular field and thus perhaps decrease major discrepancies. This practice is made possible at our institution by setting up the frozen section room in the same suite as the subspecialized pathologists' offices and maintaining a collegiate culture partial to helping each other. Thus, we recommend promoting such an open convenient pathology environment for those switching to SSSO. For the departments who do not have the frozen section and pathology offices in the same suite, perhaps access to telepathology would be useful in maintaining a low level of major discrepancies. Since institutions can decrease the discrepancy rate by monitoring this data, we also recommend such a quality assurance program throughout the process of subspecializing one's practice. Further investigation needs to be done to determine whether our institutions minor discrepancy rates decrease with monitoring frozen section discordance rates over time.

Although this is a retrospective study, the number of years and amount of frozen sections examined pre and post-SSSO strengthens our study. A weakness is that we have not taken into account Neuropathology frozen sections as the Neuropathology department's QA records are separate from the Surgical Pathology department and has remained subspecialized throughout the time periods examined in this study. Another weakness is the initiative to perform most of the gynecologic and breast surgeries at another hospital at our institution effectively eliminates those specimens from our study. The few recorded gynecologic surgical pathology specimens in this study may have an added confounding factor that these cases may not actually be subspecialized in nature. And during frozen sections of these specimens, the specialist may not be in house for consultation.

In conclusion, an important quality assurance parameter for the surgical pathology laboratory that should be monitored is the concordance rates between frozen and permanent sections. At our institution we routinely monitor this in our laboratory on a monthly basis. The Association of Directors of Anatomic and Surgical Pathology (ADASP) have established an accuracy threshold of 3% for major disagreements [9]. We instituted subspecialty sign-out in July of 2015; however, the intraoperative consultation service remained unspecialized. In this paper we compared the concordance rates of minor and major disagreements of frozen and permanent section diagnoses before and after SSSO. There was a statistically significant increase in minor discrepancies, which have no or only minor clinical significance. Importantly, there was not a statistically significant increase in major discrepancies, which do have clinical significance. In

Table 1. Summary of the discrepant cases pre-and post-subspecialty sign-out

Timeframe	Total cases of IOC	Total cases of minor discrepancies	Total cases of major discrepancies
2012-2015 (pre-SSSO)	4056	65	26
2015-2017 (post-SSSO)	2989	74	16
Total	7045	139	42

Table 2. Minor, Major, and Combined Frozen Discrepancy Rates

Discrepancy Rate	2012-2015 (pre SSSO)	2015-2017 (post SSSO)	p value
Rate of Minor Discrepancy	1.55	2.47	0.005
Rate of Major Discrepancy	0.619	0.53	1.0
Rate of Combined Discrepancy	2.17	3.0	0.014

the period after SSSO, frozen section concordance was not adversely impacted by subspecialization. It bears to be seen if this trend will be maintained after several years of SSSO and if skills and competency erode in general surgical pathology after practicing in the SSSO model.

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