

Comparison of 90-day morbidity and mortality between ileal conduit and orthotopic neobladder following radical cystectomy in a large multi-institutional database: The Canadian CBCIS experience

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ABSTRACT

Introduction: In patients undergoing radical cystectomy, ileal conduit (IC) urinary diversions are more frequently carried out than orthotopic neo-bladder reconstructions (ONB). Patients selected for IC likely have more comorbidities, advanced disease, and older age, with many being poor candidates for ONB; ONB often ends up being selected by younger and healthier patients.

Differences in complications

experienced by IC and ONB patients may be due to differences between patients or urinary diversions. To guide patient counseling and care, we aimed to assess 90-day complications and mortality for patients undergoing either procedure in a large, contemporary, Canadian cohort.

Methods: Patient information was obtained from the Canadian Bladder Cancer Information System (CBCIS), encompassing 14 academic Canadian centers. Patients who underwent radical cystectomy between February 2015 and September 2023 were included. Ninety-day complications were analyzed according to the Clavien-Dindo severity scale. Perioperative parameters and 90-day mortality were compared between IC and ONB diversion. We used rank-sum and Chi-squared exact tests as exploratory statistic. Unconditional logistic regression was used to evaluate the association between IC and ONB complications.

Results: Of 2161 patients, 1799 (83%) received an IC and 362 (16%) an ONB. Patients were followed for a median of 235 days (interquartile range [IQR] 486). The median age was 69 years (IQR 14). The age-adjusted Charlson comorbidity index (aCCI) was significantly higher in the IC group (median [IQR] 5 [2] vs. 4 [2], $p < 0.001$). The 90-day complication rate was 46% and the 90-day mortality rate was 4.3% for the entire cohort. On multivariable logistic regression, the risk of overall complications was significantly higher in the ONB than in the IC group (odds ratio 2.2, 95% confidence interval 1.7–2.8, $p < 0.001$). Ninety-day mortality was 4.9% in the IC group and 0.82% in the ONB group.

Conclusions: In this multi-institutional cohort, patients with ONB had higher odds of perioperative complications; however, there was no difference in higher-severity complications between diversions.

KEY MESSAGES

- In a large, pan-Canadian cohort, orthotopic urinary diversion is being offered to/chosen by younger and healthier subjects undergoing radical cystectomy.
- 90-day overall complications are higher in patients receiving orthotopic diversion than those receiving ileal conduit. This should weigh in on the decision to choose an orthotopic diversion with respect to the expected benefit.
- Complication severity was the same with both types of diversions
- The data did not reveal a statistically significant difference in 90-day mortality between patients receiving ileal conduit and those receiving orthotopic neo-bladder diversion after radical cystectomy.

INTRODUCTION

Radical cystectomy remains a common treatment for patients with muscle-invasive bladder cancer as well as patients with non-muscle invasive bladder cancer (NMIBC) that have failed bladder preservation approaches.(1-3) Radical cystectomy has a high risk for complications peri-operative death. (4-8) The two most common forms of urinary diversion during cystectomy are an ileal conduit (IC) and an orthotopic urinary neo-bladder (ONB) (9, 10) Although preserving body image and being associated with improved quality of life, it is perceived that ONB may come at the expense of a higher complications rate compared to IC. (11, 12)

The incidence of invasive bladder cancer peaks after age 70 (13-15), and the usual population suffering from this condition typically harbors multiple comorbidities, including cardiovascular and pulmonary conditions. (16) Patient selection/choice for the optimal diversion, which balances quality of life with complications and mortality risks, is often done based on clinician *a priori* perception, which is communicated to the patient with little supporting or even conflicting data in the literature. (6, 7)

In order to inform patient decision-making in a Canadian population, we sought to compare the 90-day complication and mortality rates between IC and ONB in a large prospectively maintained pan-Canadian cohort of patients who have undergone radical cystectomy.

METHODS

Patients

Patient information was obtained from the Canadian Bladder Cancer Information System (CBCIS), a prospectively collected and maintained registry that includes data on 7152 patients treated in 14 academic Canadian centers, with each center having institutional review board approval. The collected baseline characteristic included age, age-adjusted Charlson Comorbidity Index score, previous abdominal surgery, active smoking, pre-operative renal function, body-mass index, use of neo-adjuvant chemotherapy, and clinical stage. Complications were entered into the database using two modalities. First, inputting a binary entry (yes or no) for 12 pre-defined items (Table III). Alternatively, if the complications did not fit in any categories, they were reported narratively in an empty field under “other complications”. Data was collected prospectively in a standardized fashion by trained abstractors at each participating institution.

Outcomes

co-primary outcomes were 90-day complications, which were analyzed according to the Clavien-Dindo severity scale and 90-day mortality rates.

Statistical Analysis

We summarized continuous variables as mean, standard deviations when normally distributed, and as median with interquartile range when non-normally distributed. Categorical variables were presented as counts and percentages. Baseline characteristics between diversion groups

were compared using independent t-tests for normally distributed continuous variables, Wilcoxon rank-sum tests for non-normal continuous variables, and either chi-square or Fisher's exact tests for categorical variables, as appropriate.

To analyze complications, we performed event-level analyses to accurately account for patients who experienced multiple events. Weighted comparisons were conducted using rank-sum tests for continuous variables and chi-square exact tests for categorical variables. To identify complication-associated factors, we utilized unconditional logistic regression models adjusted for age, sex, Charlson Comorbidity Index (CCI), and neoadjuvant chemotherapy. Mortality outcomes were assessed using multivariable Cox regression, with preoperative radiation therapy excluded due to its low prevalence in the cohort. To control for the risk of Type I error arising from multiple comparisons, we applied a false discovery rate (FDR) adjustment. Additionally, we conducted age-stratified subgroup analyses (<70 and \geq 70 years) to evaluate risk differences across age groups.

To address potential confounding, we implemented propensity score matching (PSM) using a 1:1 nearest-neighbor approach without replacement. Adequate covariate balance between matched groups was confirmed by achieving a standardized mean difference (SMD) of less than 0.15. Further, we validated this analysis by logistic regression. All statistical analyses were performed using STATA 17 (StataCorp LLC, College Station, TX), with careful attention to degrees of freedom to ensure the robustness and validity of our findings.

RESULTS

A total of 2256 patients who underwent radical cystectomy between February 2015 and September 2023 were available for analysis. We excluded 95 patients with missing data. Baseline patient characteristics are presented in table I. The median age at surgery was 69 years (IQR 14). Of 2161 patients analyzed, 1670 (77%) were male. The median age-adjusted CCI (aCCI) was 5, and more patients with IC had a score of more than 5 compared to ONB (33% vs 12%, $p<0.001$). Prior radiation therapy was more prevalent in the IC group (9% vs 0.6%, $p<0.001$), whereas neo-adjuvant chemotherapy was significantly higher in patients who received ONB (50% vs 31%, $p<0.001$). The clinical stage was similar between the IC and ONB patients.

Peri-operative parameters and pathological outcomes are shown in Table Ib. Estimated blood loss was higher in patients who received ONB (837 mL vs 661 mL, $p<0.001$). Likewise, unplanned readmission was also higher in this group (48% vs 34%, $p<0.001$). Pathological T stage was higher in patients who received IC (pT3/pT4 29%/14% in IC vs 2.3%/0.9% in ONB), as well as lymph node status albeit to a lesser extent as shown in table II. Positive surgical margins were more frequent in the IC group, specifically at the urethral margin (18% in IC vs 5.8% in ONB, $p<0.001$).

Table II presents post-operative complication rates according to diversion type. It shows that overall complications, wound infections, urine/bowel leaks and lymphoceles were significantly higher in patients who received ONB (44% vs 57% $p<0.001$, 13% vs 22% $p<0.001$, 4.0% vs 17% $p<0.001$ and 2% vs 5.5% $p<0.001$ respectively). Only hemorrhage, pneumonia,

and delirium occurred more frequently in IC, without this reaching statistical significance. Other unclassified complications amounted to 107 (14%) of total complications and did not reveal differences with respect to diversion type.

Multivariable analysis for various complications is shown in Table III. The association of any complication with ONB is still noted (OR=2.0, 95% CI 1.53-2.63 $p<0.001$), as well as the higher rates of wound infection, urine/bowel leaks, and lymphoceles in patients who received ONB (OR=1.96, 95% CI 1.41-2.72 $p<0.001$; OR=4.84, 95% CI 3.37-6.96 $p<0.001$; and OR=2.91, 95% CI 1.53-5.54 $p = 0.001$ respectively).

The severity of complications with respect to diversion is presented in table IV. There were 99 (14.5%) complications with unknown Clavien-Dindo scores. Of the remaining 586 complications that were analyzed, we could not show an association between type of diversion and complication severity overall. However complication severity was particularly higher in IC for hemorrhage (0.6% vs 0%, $p = 0.07$), whereas it was higher in ONB for fistulas/leaks (1.5% vs 4.1%, $p = 0.004$). When including missing data for each of these two complications, the difference between IC and ONB was still present for fistulas/leaks but was absent for hemorrhage. Otherwise, the analysis with or without missing data did not yield any difference for the other listed complications.

Analyzing data with respect to age (less than 70 years $n=1197$, and more than 70 years $n=945$, data shown in appendix 3) ONB and smoking were significantly associated with increased odds of In the older than 70 years group, while these associations were weaker in the younger group.

Ninety-day mortality could not be meaningfully compared in a multivariable analysis between IC and ONB, given the low rate of events in patients who received ONB ($n=3$). Absolute 90-day mortality numbers and rates are presented in Table II. Mortality was 4.9% in patients who received IC and 0.82 % in those who received ONB.

DISCUSSION

Comparing diversions in patients undergoing radical cystectomy is fraught with selection bias due to patient preference when choosing a procedure and the way surgeons present the patient with options with respect to their overall condition, age, and disease stage. In this study, we sought to contribute to the body of literature by assessing a large, multi-centric Canadian database with respect to 90-day complications and mortality. We further sought to find preoperative determinants of worse outcomes for each IC and ONB in order to facilitate clinical decision-making.

Our results show that patients receiving ONB were significantly younger (86% of ONB patients were less than 70) and had fewer comorbidities (Score higher than 5 on the Charlson comorbidity scale 33% in IC vs 12% in ONB, $p<0,0001$). Analysis by age group showed that ONB portend high complications in the older patient (more than 70 years old) with smoking history. This suggests that ONB should be offered only after careful consideration of the overall clinical picture in this type of patients (Appendix 3).

Outcomes of ileal conduit vs. orthotopic neobladder post-radical cystectomy

In this study, 90-day complication rate (44% in IC and 57% in ONB) is similar to those reported in the literature: In a systematic review and meta-analysis of 32 publications (16 prospective and 16 retrospective case-control/cohort studies) grouping 46 787 patients and assessing cohorts from globally widespread countries (including the US, Japan, Chili, Germany, Poland, Italy, Korea, Sweden, and India among others) Browne et al. compared IC to ONB with respect to four outcomes: Quality of life, long-term durability, complication rate, mortality, and length of stay between the two groups.(17) Complication rates were reported to be 61.9% in IC vs 60.1% in ONB, with an odds ratio of 1.16 ($p < 0.01$). This stands in contrast to our results, but it may also be noted that although statistically significant, a 1.8% difference may not clinically influence decision-making substantially, especially in light of the heterogeneity of studies that were used to generate the data. Furthermore, this meta-analysis included patients who underwent cystectomy for reasons other than bladder cancer. Our results arguably evaluate a more homogenous set of patients being treated according to national guidelines and may more appropriately apply to a Canadian context.

Even though large North American and European cohort studies report similar results to the present study, with ONB presenting a higher complication rate (18, 19), other extensive studies assessing patients in similar environments and geographic regions suggest an equivalence between IC and ONB in terms of complications rate, if not a slight superiority of ONB.(8, 20-23).

Unplanned readmission was higher in the ONB group (48% vs 34%, $p < 0,0001$), implying a higher complication rate for patients receiving ONB. On the other hand, the severity of complications, according to the Clavien-Dindo scale, did not show a statistically significant difference between the two groups overall except for fistulas/leaks.

In this study, 90-day mortality was 4,9% in patients who received an IC and 0,82% in patients who received an ONB ($p < 0,0001$). Browne et al's meta-analysis favored ONB (9.6% vs. 1.6%, OR 6.29 $p < 0.01$), albeit the authors stress that the risk of death is possibly related to older age and higher-grade tumors in the IC group, which tend to bias results.(17) Although the disease stage was similar in our study between groups, older age in the IC group may explain the observed trend. More recent data suggest equivalence in mortality rates between the two approaches.(18)

Overall, disparity in published results may suggest that geographical regions and studied populations should influence the information that patients are given when being counseled in a tailor-made approach. In that sense, using our data in a Canadian population, IC seems to portend fewer complications than ONB, albeit possibly with a price in terms of altered lifestyle. Future endeavors should arguably assess further use of biomarkers combined with artificial intelligence tools for more informative and discriminating prediction of outcomes.

Limitations of this study include selection bias. Although the data collection is prospective and multi-centric, controlling for confounding factors was carried out using multivariable analysis, which does not guarantee the elimination of such bias. We carried out

Outcomes of ileal conduit vs. orthotopic neobladder post-radical cystectomy

alternative statistical analysis using inverse probability of treatment weighting (IPTW), which did not yield different outcomes, suggesting a reliable and reproducible result. Also, the database did not account for ERAS protocol application, which could influence 90-day complication rates. As for data completeness, only 1.5% of the information was missing; this is considered relatively minor and should not influence the conclusions. Additionally, Clavien-Dindo scores were missing for about 14.5% of cases, but no considerable difference in the final results was elicited when the analysis was carried out with the missing data. It would probably have also been significant to report long term data such as OS and quality of life data. Our overall survival seemed to favor ONB, but given the lack of long term followup for all patients, we were not able to draw any meaningful and reliable conclusions from the data. More granular analysis taking into account male to female comparisons as well as robotic vs open approaches could not be carried out due to small numbers of female patients receiving ONB and very small number of robotic surgeries. Finally, quality of life data is lacking from our dataset and would have been of significant value for patient counseling.

CONCLUSIONS

Peri-operative complications following radical cystectomy remain significant. The 90-day complication rate is higher in patients receiving orthotopic neobladder in our multi-centric patient cohort. On the other hand, no overall difference could be demonstrated in the severity of these complications in patients who received orthotopic neobladders versus those who received ileal conduits except for fistulas and leaks. The long-term benefits of orthotopic diversion should still be considered when selecting a urinary diversion.

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9204 FIGURES AND TABLES

| Table 1. Baseline characteristics | | | |
|--|--------------------|--------------------|------------------|
| | IC (n=1799) | ONB (n=362) | p |
| Male gender | 1362 (76) | 308 (86) | <0.001 |
| Age at surgery (yrs), | | | |
| Mean (SD) | 66.4 (16) | 58.6 (16) | <0.001 |
| Median (25th–75th) | 62 (55–63) | 61 (55–68) | |
| ≤70, n (%) | 889 (50) | 308 (86) | <0.001 |
| >70, n (%) | 893 (50) | 52 (14) | |
| aCCI | | | |
| Mean (SD) | 3.9 (1.6) | 4.9 (2.0) | <0.001 |
| Median (25th–75th) | 5 (4–6) | 4 (3–5) | |
| 0 [≤2], n (%) | 155 (9.3) | 59 (19) | |
| 1 [3–5], n (%) | 962 (57) | 223 (70) | |
| 2 [≥5], n (%) | 559 (33) | 37 (12) | |
| Previous abdominal/pelvic surgery, n (%) | 103 (5.8) | 12 (3.3) | 0.16 |
| Previous abdominal/pelvic RT, (n (%)) | 160 (9.0) | 2 (0.6) | <0.001 |
| Active smoking (current smoker), n (%) | 436 (24) | 98 (27) | 0.047 |
| Pre-op serum creatinine | | | |
| Mean (SD) | 103.3 (42) | 93.4 (24) | 0.0052 |
| Median (25th–75th) | 94 (77–119) | 88 (76–107) | |
| NAC, n (%) | 561 (31) | 180 (50) | <0.001 |
| BMI, n (%) | | | |
| Normal | 712 (40) | 142 (39) | 0.2 |
| Overweight | 534 (30) | 123 (34) | |
| Obese | 312 (18) | 61 (17) | |
| Clinical T stage, n (%) | | | |
| cT0 | 2 (0.12) | 0 (0.0) | |
| cTa | 118 (7.2) | 30 (8.8) | |
| CIS | 97 (5.9) | 14 (4.1) | |
| cT1 | 332 (20) | 76 (22) | |
| cT2 | 907 (57) | 185 (55) | |
| cT3 | 86 (5.4) | 22 (6.6) | |
| cT4 | 45 (2.8) | 7 (2.1) | 0.6 |
| Clinical node-positive disease, n (%) | 90 (8.4) | 16 (7.4) | 0.6 |

Clinical stage is the worst diagnosis before the cystectomy. Due to missing information on specific variables, the total numbers may not sum accurately. aCCI: age-adjusted Charlson comorbidity index; BMI: body mass index; IC: ileal conduit; NAC: neoadjuvant chemotherapy; ONB: orthotopic neobladder; RT: radiation therapy; SD: standard deviation.

| Table 1B. Pathologic and perioperative outcomes | | | |
|--|--------------------|--------------------|------------------|
| | IC (n=1799) | ONB (n=362) | p |
| Perioperative outcomes | | | |
| EBL (ml) | | | |
| Mean (SD) | 661 (552) | 837 (614) | <0.001 |
| Median (25th–75th) | 600 (400–1000) | 750 (500–1100) | |
| Length of hospital stay (d) | | | |
| Mean (SD) | 12.8 (6) | 17.6 (7) | 0.014 |
| Median (25th–75th) | 8 (7–13) | 9 (7–13) | |
| Unplanned readmission (90 d), n (%) | 264 (34) | 99 (48) | <0.001 |
| Adjuvant chemotherapy), n (%) | 115 (6.4) | 26 (7.2) | 0.6 |
| Mortality (90 d), n (%) | 89 (4.9) | 3 (0.82) | <0.001 |
| Pathologic outcomes, n (%) | | | |
| Histology | | | |
| Urothelial | 1014 (66) | 213 (77) | |
| Non-urothelial | 101 (6.6) | 14 (5.0) | |
| Mixed | 426 (28) | 51 (18) | 0.002 |
| Pathological T stage, n (%) | | | |
| pT0 | 167 (9.6) | 64 (18) | |
| pTa | 53 (3.1) | 14 (4.0) | |
| pTis | 167 (9.6) | 64 (18) | |
| pT1 | 179 (10) | 48 (14) | |
| pT2 | 350 (20) | 48 (14) | |
| pT3 | 505 (29) | 86 (23) | |
| pT4 | 239 (14) | 8 (0.9) | <0.001 |
| Pathological N stage, n (%) | | | |
| pN0 | 1147 (66) | 265 (76) | |
| pN1 | 206 (12) | 34 (9.8) | |
| pN2 | 225 (13) | 30 (8.6) | |
| pN3 | 58 (3.4) | 5 (1.4) | |
| pNx | 80 (4.6) | 14 (4.0) | 0.005 |
| Positive surgical margin, n (%) | | | |
| Any site | 270 (18) | 16 (5.8) | <0.001 |
| Bladder | 81 (4.5) | 7 (1.9) | 0.024 |
| Ureter | 49 (2.8) | 4 (1.1) | 0.068 |
| Urethra | 143 (8.0) | 6 (1.7) | <0.001 |
| Lymph nodes removed, mean (SD) | 19.0 (11) | 22.1 (11) | <0.001 |

EBL: estimated blood loss; IC: ileal conduit; IQR: interquartile range, ONB: orthotopic neobladder; SD: standard deviation.

| Complications | IC (n=1799) | % | ONB (n=362) | % | p | |
|--|------------------------|----------------|------------------------|----------------|------------------|------------------|
| Any complications | 783 | 44 | 208 | 57 | <0.001 | |
| MI/DVT/PE/CVA | 137 | 7.6 | 33 | 9.1 | 0.3 | |
| Wound infections | 241 | 13 | 81 | 22 | <0.001 | |
| Fascial dehiscence | 62 | 3.5 | 16 | 4.4 | 0.3 | |
| Haemorrhage | 31 | 1.7 | 3 | 0.83 | 0.2 | |
| Pneumonia | 45 | 2.5 | 7 | 1.9 | 0.5 | |
| Delirium | 62 | 3.5 | 9 | 2.5 | 0.3 | |
| Ileus | 298 | 17 | 62 | 17 | 0.8 | |
| Bowel/urine leak | 72 | 4.0 | 61 | 17 | <0.001 | |
| Lymphocele | 35 | 2.0 | 20 | 5.5 | <0.001 | |
| Failure to thrive/ weakness/malnutrition | 10 | 0.56 | 3 | 0.83 | 0.5 | |
| Electrolyte-acid imbalance | 18 | 1.0 | 4 | 1.1 | 0.9 | |
| Renal failure | 35 | 2.0 | 8 | 2.2 | 0.8 | |
| Pain control issues | 9 | 0.50 | 4 | 1.1 | 0.2 | |
| Other complications | 107 | 6.0 | 30 | 8.3 | 0.8 | |
| EBL (ml) | Mean [SD] | 661 (552) | | 837 (614) | | <0.001 |
| | Median [25th–75th] | 600 (400–1000) | | 750 (500–1100) | | |
| Length of hospital stay (d) | Mean [SD] | 12.8 (6) | | 17.6 (7) | | 0.014 |
| | Median [25%–75%] | 8 (7–13) | | 9 (7–13) | | |
| Unplanned readmission (90 d) | N (%) | 264 (34) | | 99 (48) | | <0.001 |
| Mortality (90 d) | N (%) | 89 (4.9) | | 3 (0.82) | | <0.001 |

CVA: cerebrovascular accident; DVT: deep venous thrombosis; IC: ileal conduit; MI: myocardial infarction; ONB: orthotopic neobladder; PE: pulmonary embolism; SD: standard deviation.

| Table 3. Multivariable logistic regression analysis with adjusted odds ratio for various complications according to diversion type. | | | |
|--|----------------------|------------------|------------------|
| Complications | Multivariable | | |
| | OR | 95% CI | p |
| Any complications | | | |
| IC | 1.00 | | |
| ONB | 2.00 | 1.53-2.63 | <0.001 |
| MI/DVT/PE/CVA | | | |
| IC | 1.00 | | |
| ONB | 1.41 | 0.88-2.22 | 0.14 |
| Wound infection | | | |
| IC | 1.00 | | |
| ONB | 1.96 | 1.41-2.72 | <0.001 |
| Fascial dehiscence | | | |
| IC | 1.00 | | |
| ONB | 1.71 | 0.90-3.22 | 0.10 |
| Hemorrhage/bleeding | | | |
| IC | 1.00 | | |
| ONB | 0.58 | 0.17-2.02 | 0.4 |
| Pneumonia/pulmonary | | | |
| IC | 1.00 | | |
| ONB | 0.92 | 0.37-2.30 | 0.9 |
| Delirium/neurologic | | | |
| IC | 1.00 | | |
| ONB | 0.94 | 0.43-2.01 | 0.9 |
| Lleus-related | | | |
| IC | 1.00 | | |
| ONB | 1.07 | 0.75-1.51 | 0.7 |
| Bowel/urine leaks/fistula | | | |
| IC | 1.00 | | |
| ONB | 4.84 | 3.37-6.96 | <0.001 |
| Lymphocele | | | |
| IC | 1.00 | | |
| ONB | 2.91 | 1.53-5.54 | 0.001 |
| Renal failure | | | |
| IC | 1.00 | | |
| ONB | 1.30 | 0.56-3.04 | 0.5 |
| Electrolytes-acid imbalances | | | |
| IC | 1.00 | | |
| ONB | 1.47 | 0.30-7.10 | 0.6 |
| Failure to thrive/ weakness/malnutrition | | | |

Outcomes of ileal conduit vs. orthotopic neobladder post-radical cystectomy

| | | | |
|---------------------|------|-----------|------|
| IC | 1.00 | | |
| ONB | 2.24 | 0.39-9.07 | 0.4 |
| Pain control issues | | | |
| IC | 1.00 | | |
| ONB | 3.16 | 0.74-14.1 | 0.12 |
| Other complications | | | |
| IC | 1.00 | | |
| ONB | 1.11 | 0.68-1.83 | 0.7 |

Multivariable analysis was adjusted for age, adjusted Charlson comorbidity index, sex, smoking, hospital stay, and neoadjuvant chemotherapy. CI: confidence interval; CVA: cerebrovascular accident; DVT: deep venous thrombosis; IC: ileal conduit; MI: myocardial infarction; ONB: orthotopic neobladder; OR: odds ratio; PE: pulmonary embolism; SD: standard deviation.

DRAFT