HOW TO WRITE A PAPER

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- DIRECTOR; CALCUTTA CHIRURGIAE COLLECTIVE
- VISITING SURGEON;

  CMRI C K BIRLA HOSPITALS

  WOODLANDS MUTISPECIALTY HOSPITAL

BABY STEPS

- Do you have something worthwhile to say?

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- What sort of paper would you like to write and in which Journal?

INITIAL STEPS

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EDITORIAL/LEAD ARTICLES

ORGINAL ARTICLES

REVIEW ARTICLE & METAANALYSIS

SURGICAL TECHNIQUES & INNOVATIONS

CASE REPORT

IMAGES IN SURGERY

CONSENSUSSTATEMENTS/GUIDELINES/POPULATION SURVEYS

LETTER TO THE EDITOR

OBITUARIES

VIEWS/CRITICAL APPRAISAL/HYPOTHESIS

INITIAL STEPS

- Is what you want to say
  - Original?
  - What are recent researches on this topic?
  - Is it a current “hot” topic?

CHECK LIST

Good idea to DO your research before writing

- Check what you want to say-
  - Have you verified your results with appropriate analysis?
  - Have you verified the significance of your findings?
  - Have you checked the validity and verification of your methods and measurements?
  - Have you defined the scope and limitations of your methods?
  - Are you providing solutions to a contentious topic?

IF YES!

YOU ARE READY TO SHAPE YOUR ARTICLE!

REPORTING GUIDELINES BASED ON MAIN STUDY TYPES

• Randomised trials	CONSORT	Extensions
• Observational studies	STROBE	Extensions
• Systematic reviews	PRISMA	Extensions
• Study protocols	SPIRIT	PRISMA-P
• Diagnostic/prognostic studies	STARD	TRIPOD
• Case reports	CARE	Extensions
• Clinical practice guidelines	AGREE	RIGHT
• Qualitative research	SRQR	COREQ

RANDOMISED TRIAL – CONSORT CONSOLIDATED STANDARDS OF REPORTING TRIALS

Section/Topic	Item No	Checklist item	page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[45 65])	

RANDOMISED TRIAL - CONSORT

Section/Topic	Item No	Checklist item
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons

RANDOMISED TRIAL - CONSORT

Section/Topic	Item No	Checklist item
Introduction		
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines

Section/Topic	Item No	Checklist item
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses

RANDOMISED TRIAL - CONSORT

Section/Topic	Item No	Checklist item
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

RANDOMISED TRIAL - CONSORT

Section/Topic	Item No	Checklist item
Results		
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[42])

RANDOMISED TRIAL - CONSORT

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Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[42])

RANDOMISED TRIAL - CONSORT

Section/Topic	Item No	Checklist item
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

STEP I –PRIMARY LAYOUT – PLANNING THE FOUNDATION

- THE PREAMBLE
  - TITLE
  - AUTHORS
  - ABSTRACT
  - KEYWORDS

- TITLE – Concise and informative. Allows for proper indexing and searching.
- AUTHORS – Names, affiliations, clear active email of corresponding author. Author ORCID if available.

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Help

STEP I –PRIMARY LAYOUT – PLANNING THE FOUNDATION

- THE PREAMBLE
  - TITLE
  - AUTHORS
  - ABSTRACT
  - KEYWORDS
- ABSTRACT- Usually a synopsis of about 150-200 words. Should not contain any undefined abbreviations or unspecified references.
- KEYWORDS – 4 to 6 keywords WHICH CAN BE USED FOR INDEXING PURPOSES.

STEP I –PRIMARY LAYOUT –PLANNING THE FOUNDATION

- MAIN TEXT
- I
  - Introduction.
- M
  - Methods.
- R
  - Results.
- A
  - And
- D
  - Discussion and Conclusions.

STEP I –PRIMARY LAYOUT – PLANNING THE FOUNDATION

- Acknowledgements.
- References.
- Supplementary materials.

STEP II = SCAFFOLDING

STEP II – SCAFFOLDING

- LENGTH
- (IJS suggests 3000 words, 30 references, 5 tables and illustrations)
- Original work attestation a MUST.

SMART TIPS “ MR FIAT MODE”

- M • METHODS
- R • RESULTS
- F • FACTS – DISCUSSION & CONCLUSIONS

- I • INTRODUCTION
- A • ABSTRACT
- T • TITLE

STEP III – INTERIOR STRUCTURE (METHODS)

- METHODS:-
- Bulk of the paper robust with enough clear information so that it is REPRODUCIBLE.

STEP III – INTERIOR STRUCTURE (METHODS)

- METHODS -- THE 7 STEPS

1. Define population and sampling
2. Describe the instrumentation
3. Describe the procedures and the time frame
4. Describe the analysis plan
5. Describe the approaches so that the validity and reliability can be checked.
6. Assumptions to be stated.
7. Scope and limitations of the methodology must be stated.

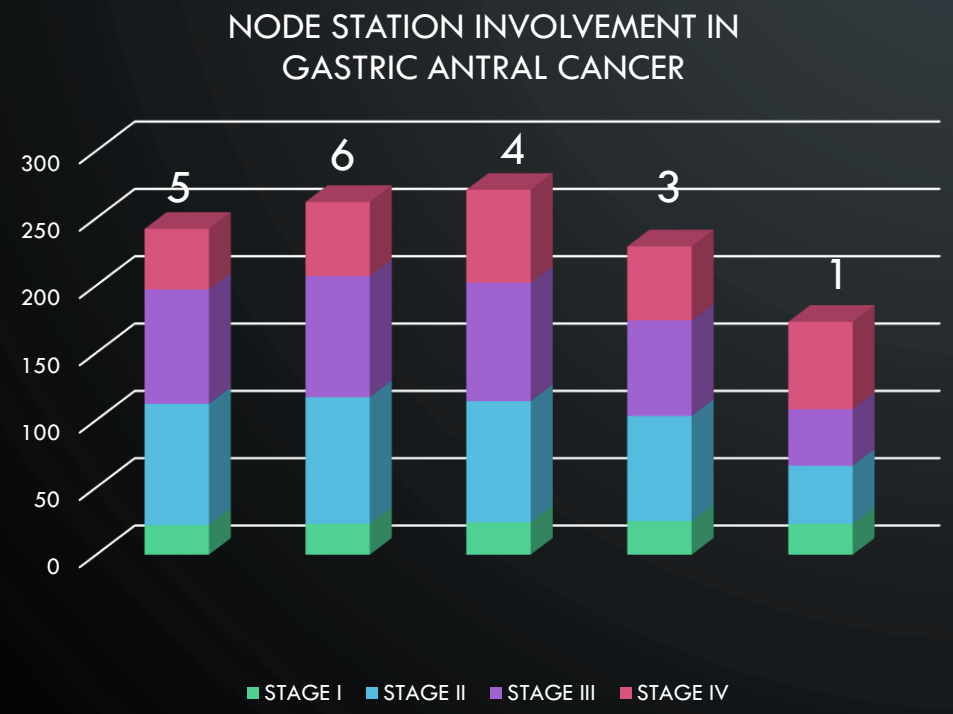
STEP IV - INTERIOR DESIGNS (RESULTS)

- RESULT:-
- Figures and tables to summarize data
- Statistical analysis to be shown
- Confirm reliability
- Justify your choice of methods
- Define the limitations of the methods

STEP IV - INTERIOR DECORATIONS (RESULTS)

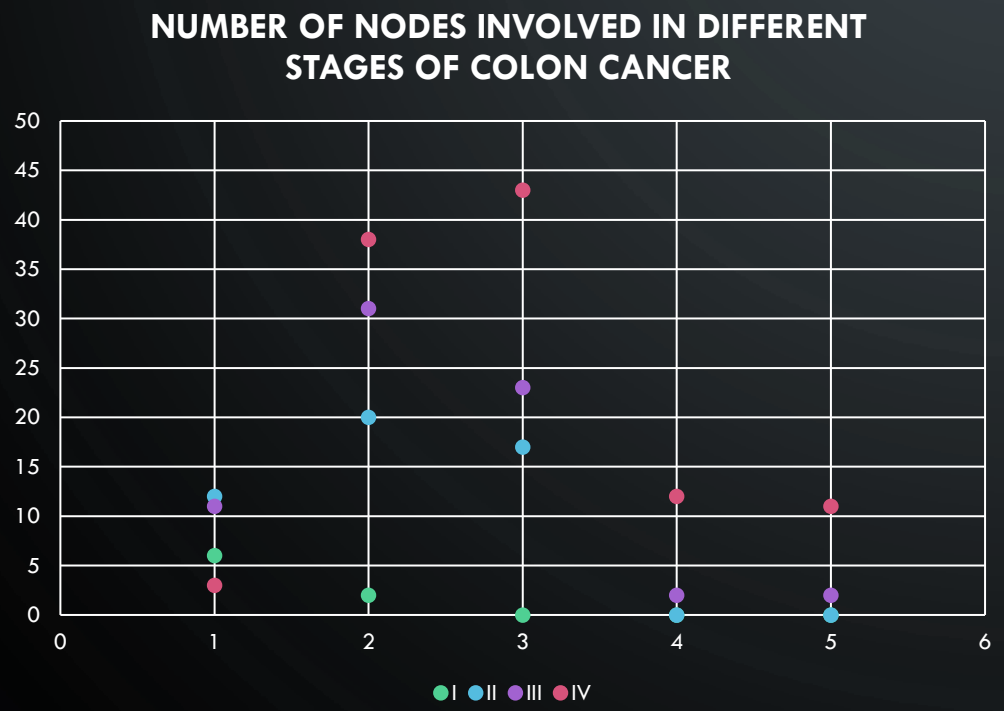
- FIGURES & TABLES:-
- Great concise eye-catching way to present your results!!!
- BUT - must be able to stand alone with its caption completely understandable without needing to read the manuscript
- Data should be easy to interpret
- Colour ONLY if absolutely MANDATORY.
- Must not repeat the entire METHODS though.

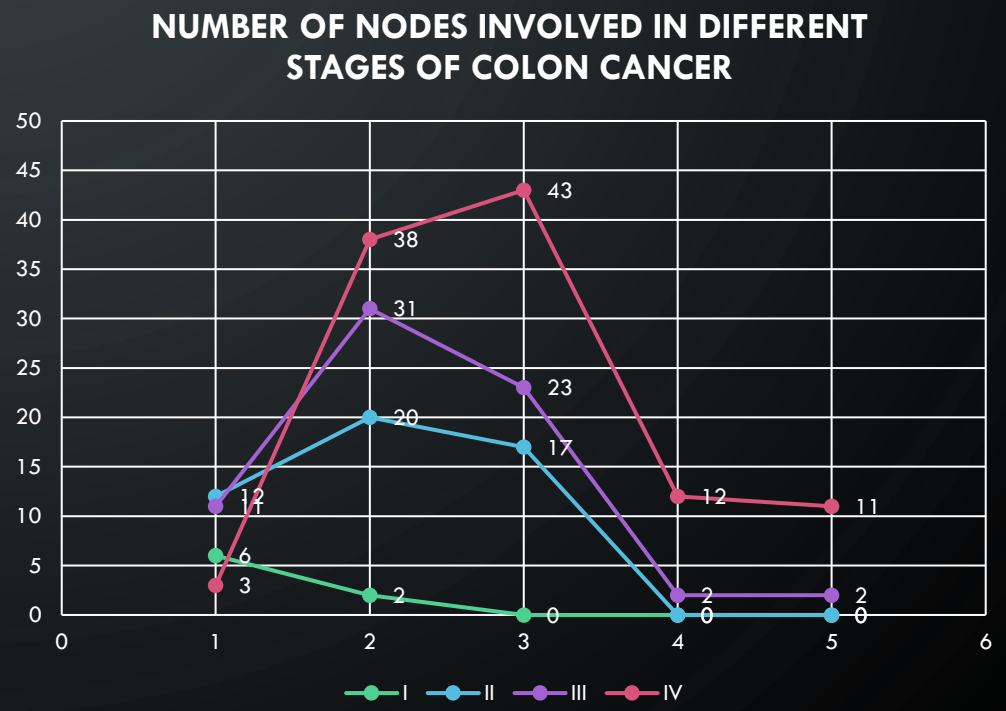
EXAMPLE – sampling of node stations in carcinoma antrum of stomach



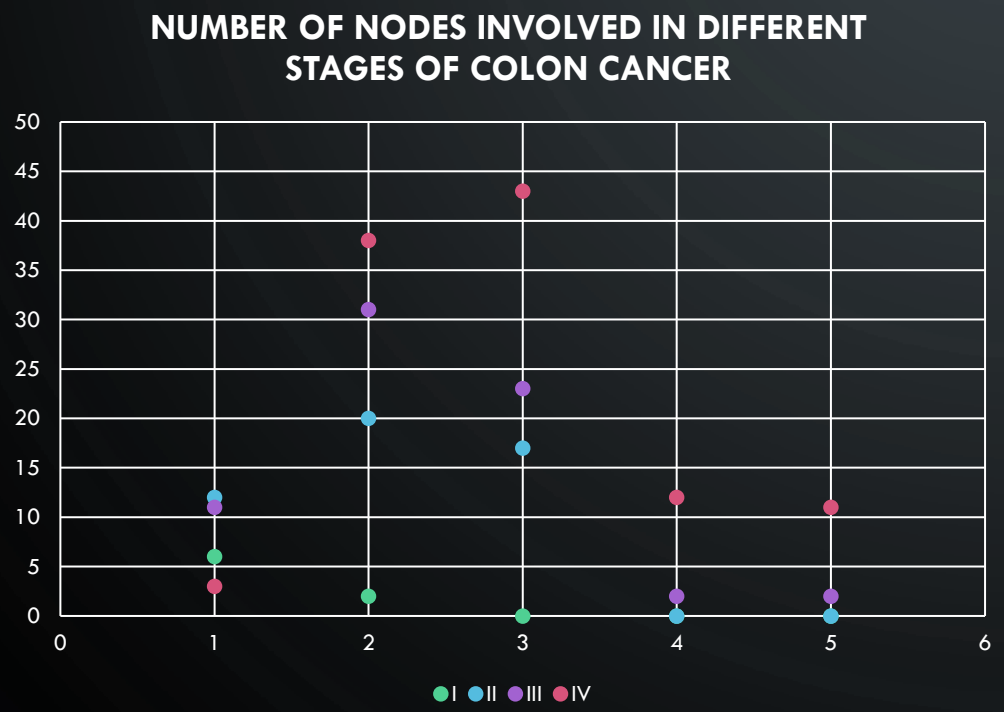
NODE STATION	5	6	4	3	1
STAGE I	22	23	24	25	23
STAGE II	90	94	90	78	43
STAGE III	85	90	88	71	42
STAGE IV	45	55	69	55	65

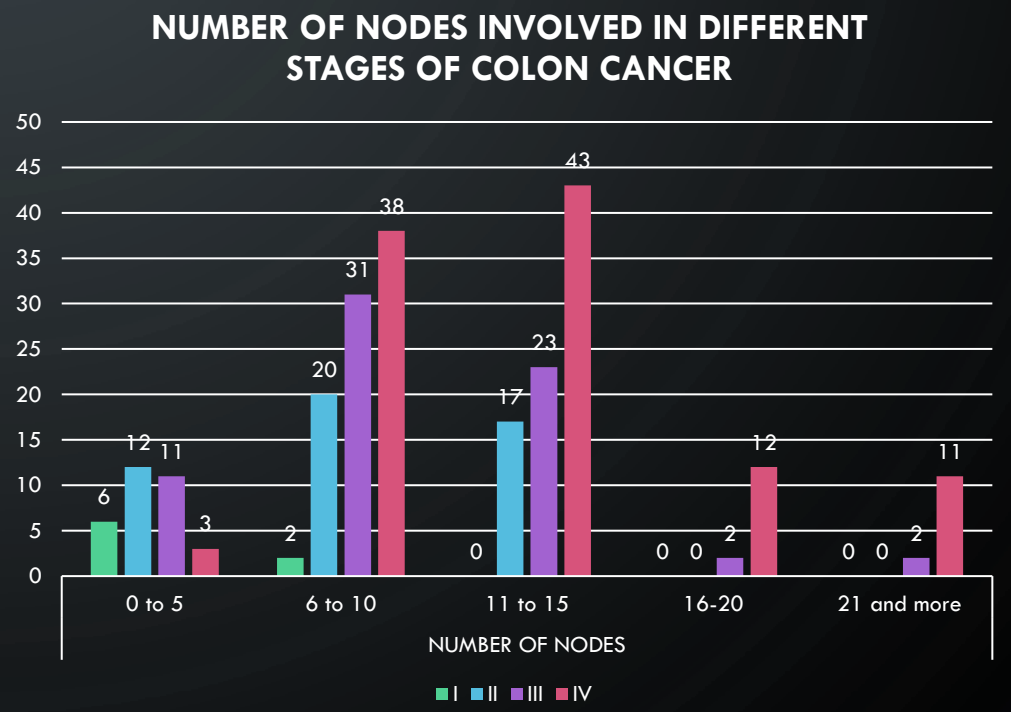
EXAMPLE Number of nodes involved in different stages of colon cancer





EXAMPLE Number of nodes involved in different stages of colon cancer

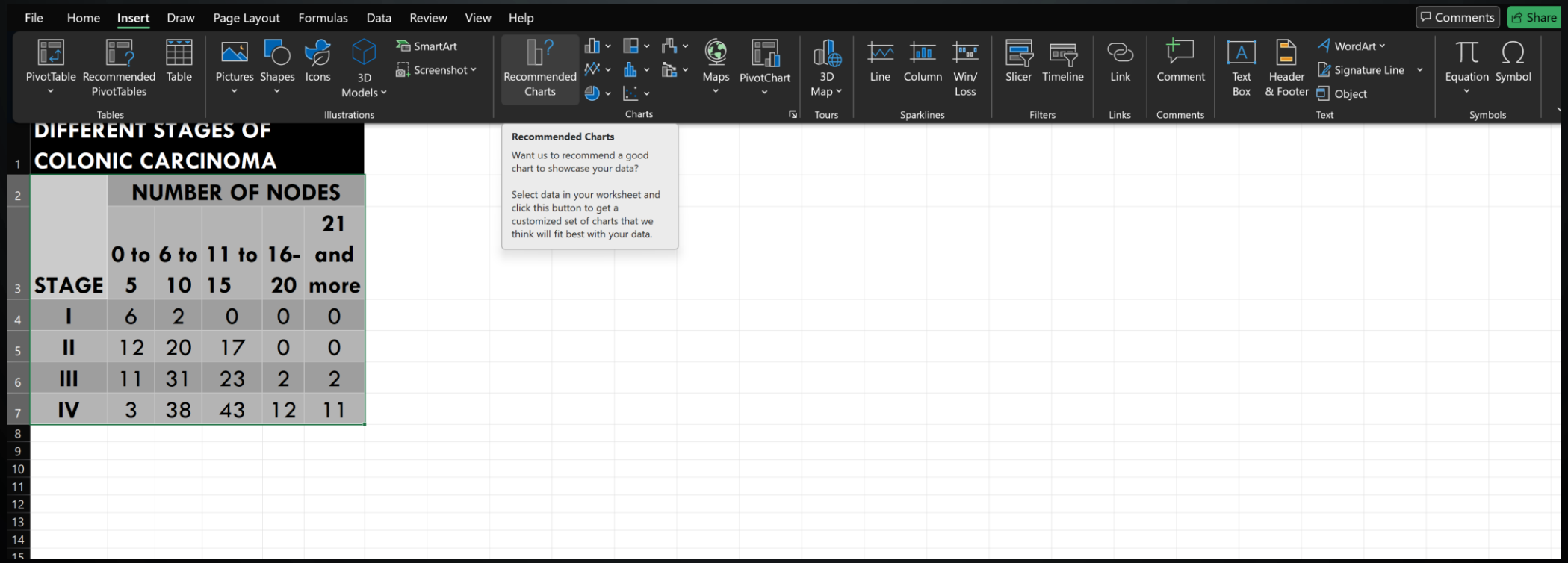




COLON CANCER – NUMBER OF NODES INVOLVED IN DIFFERENT STAGES

NUMBER OF NODES IN DIFFERENT STAGES OF COLONIC CARCINOMA					
STAGE	NUMBER OF NODES				
	0 to 5	6 to 10	11 to 15	16-20	21 and more
I	6	2	0	0	0
II	12	20	17	0	0
III	11	31	23	2	2
IV	3	38	43	12	11

USING AN EXCEL SHEET



DIFFERENT STAGES OF COLONIC CARCINOMA					
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USING AN EXCEL SHEET

File Home Insert Draw Page Layout Formulas Data Review View Help — Comments — Share

A2 | STAGE

NUMBER OF NODES IN DIFFERENT STAGES OF COLONIC CARCINOMA

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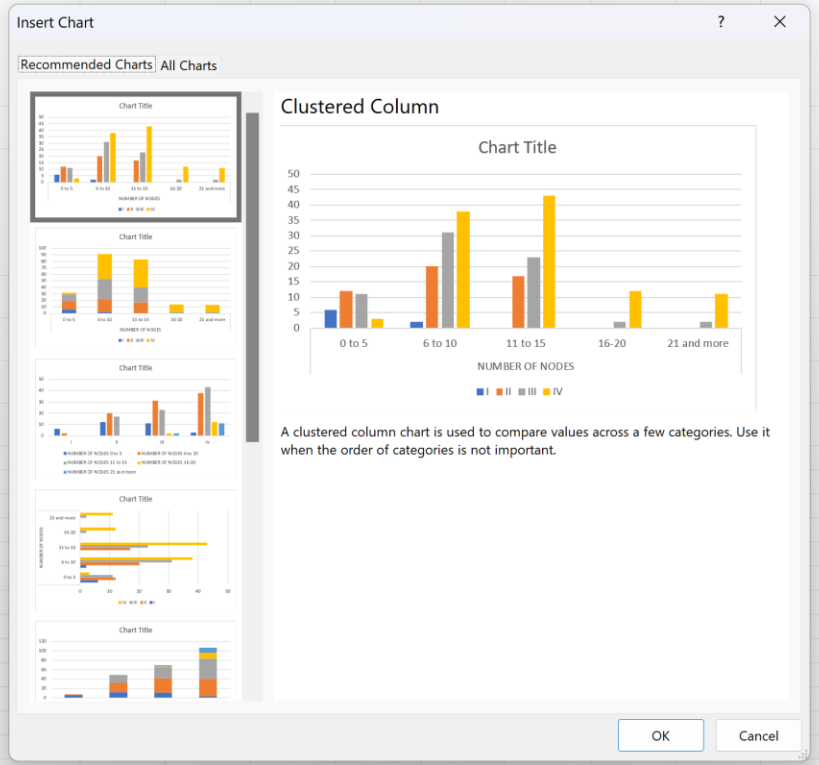

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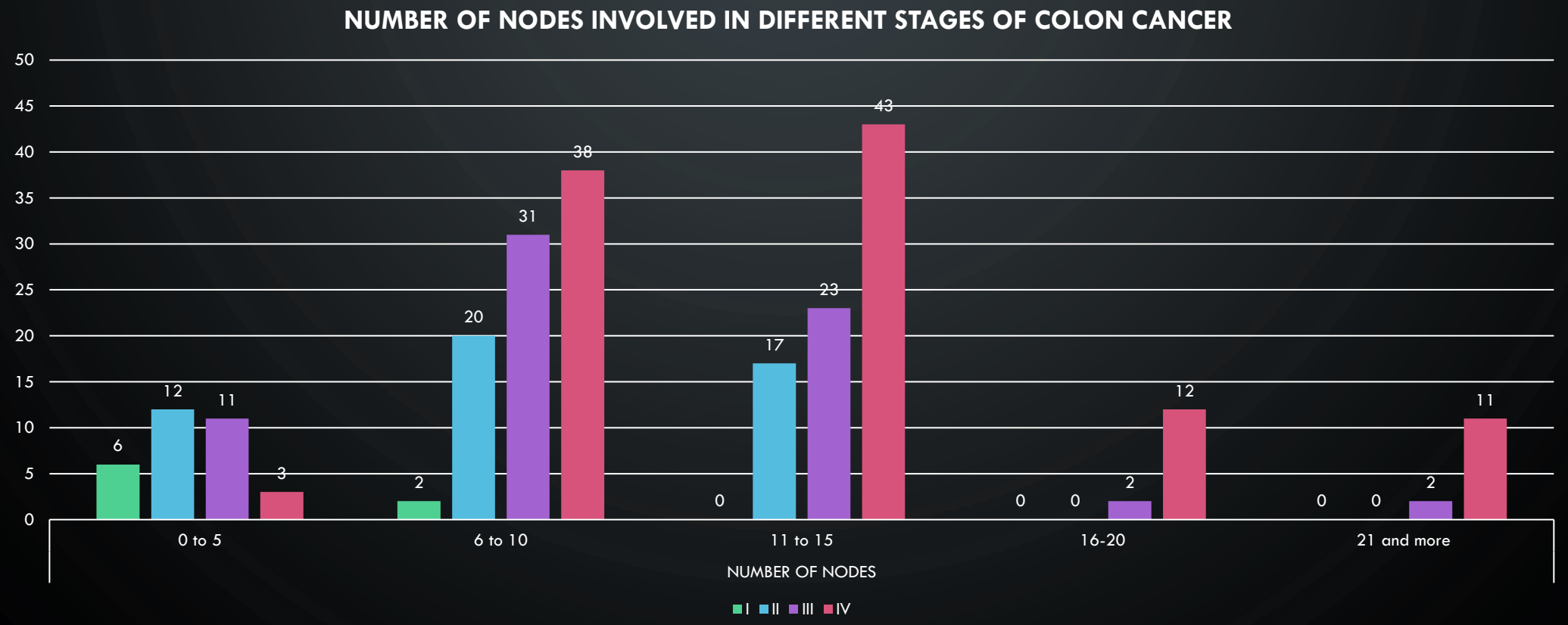


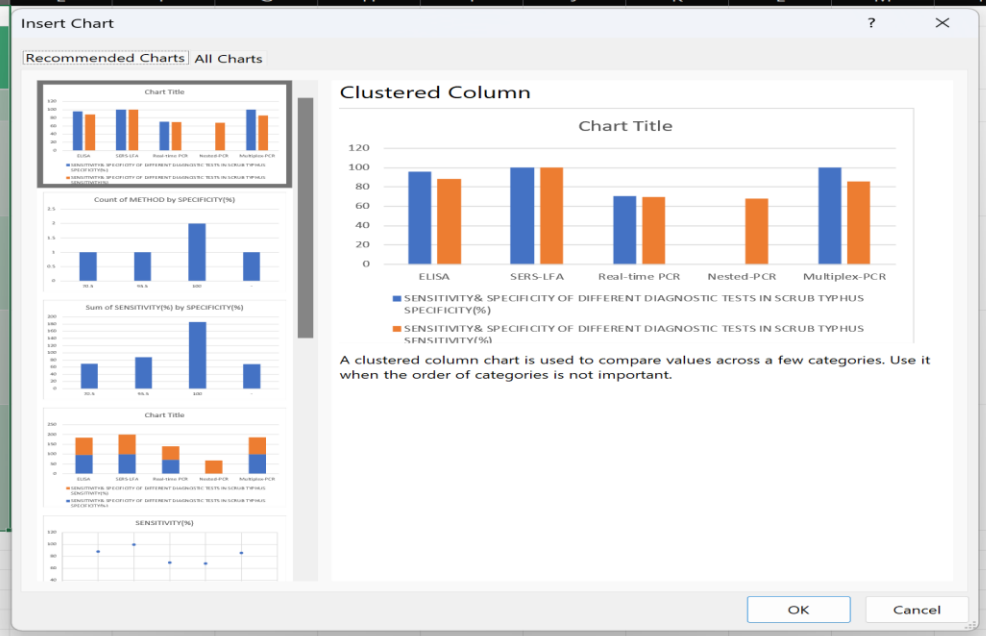
USING AN EXCEL SHEET COMPARISON OF SPECIFICITY & SENSITIVITY OF DIFF DIAGNOSTIC MODALITIES IN SCRUB TYPHUS

METHOD	BIOMARKER	SPECIFICITY(%)	SENSITIVITY(%)
ELISA	IgM	95.5	88
SERS-LFA	56 kDa TSA	100	100
Real-time PCR	HtrA	70.5	69.7
Nested-PCR	groEL	-	68.2
Multiplex-PCR	groEL/47kDa htrA	100	86

USING AN EXCEL SHEET COMPARISON OF SPECIFICITY & SENSITIVITY OF DIFF DIAGNOSTIC MODALITIES IN SCRUB TYPHUS

SENSITIVITY& SPECIFICITY OF DIFFERENT DIAGNOSTIC TESTS IN SCRUB TYPHUS

METHOD	BIOMARKER	SPECIFICITY(%)	SENSITIVITY (%)
ELISA	IgM	95.5	88
SERS-LFA	56 kDa TSA	100	100
Real-time PCR	HtrA	70.5	69.7
Nested-PCR	groEL	-	68.2
Multiplex-PCR	groEL/47kDa htrA	100	86



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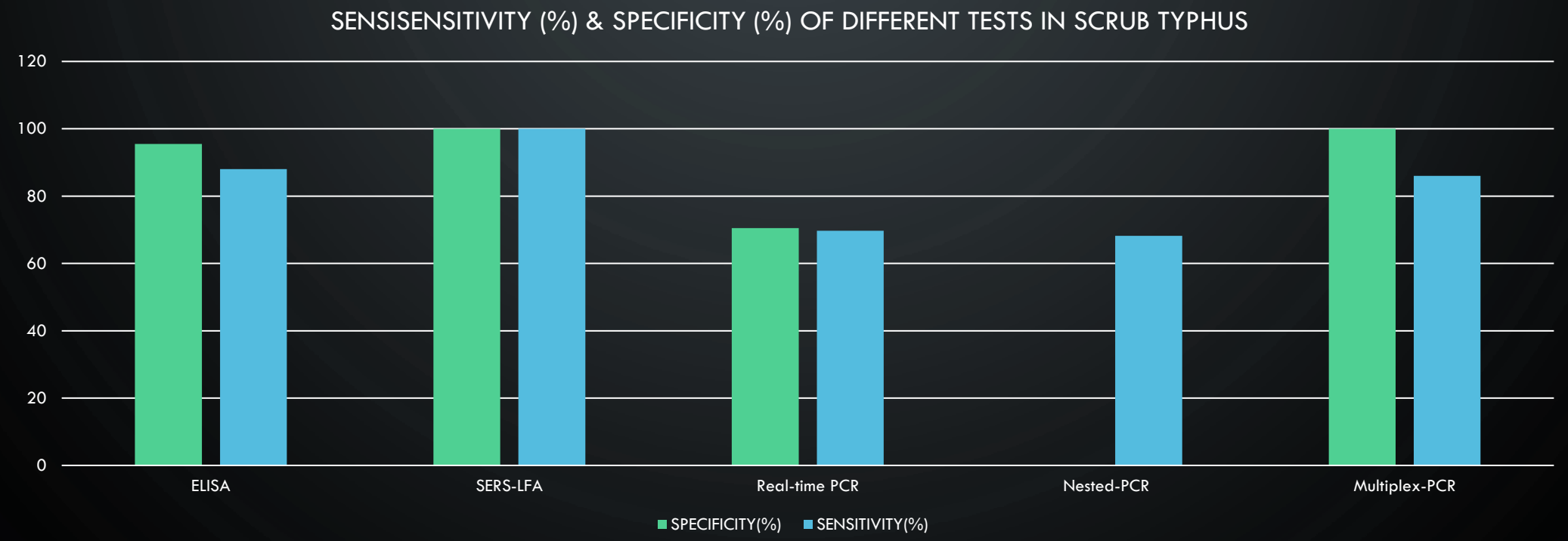
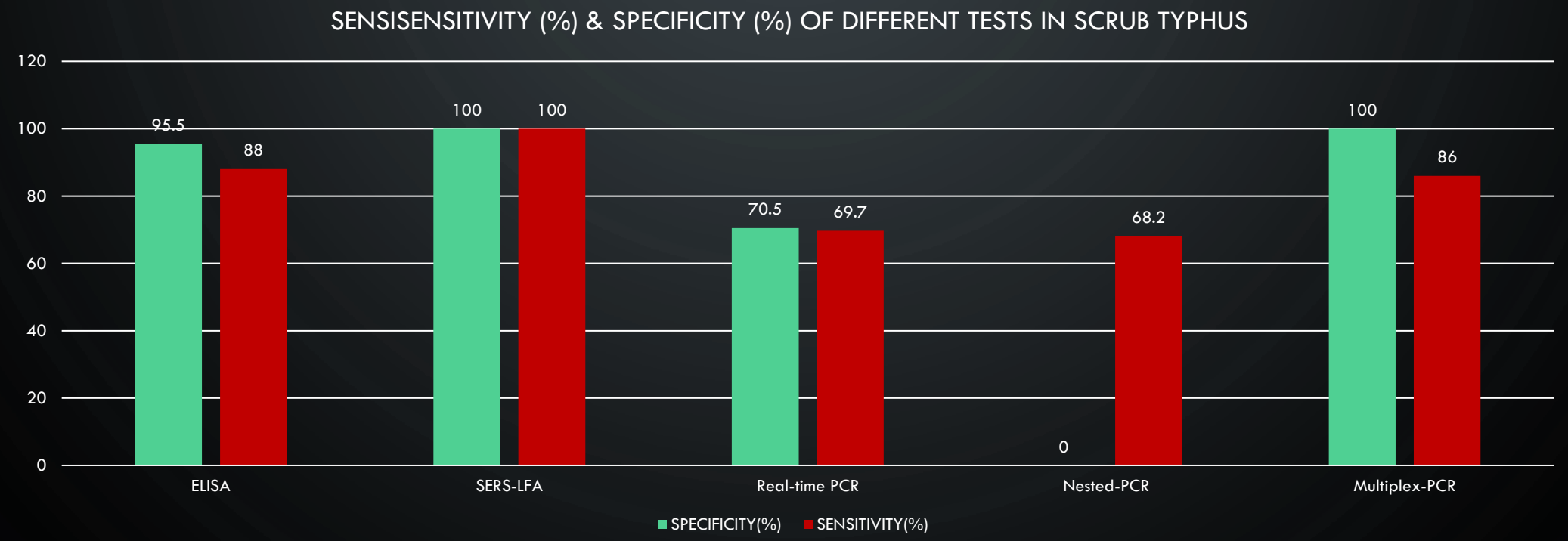
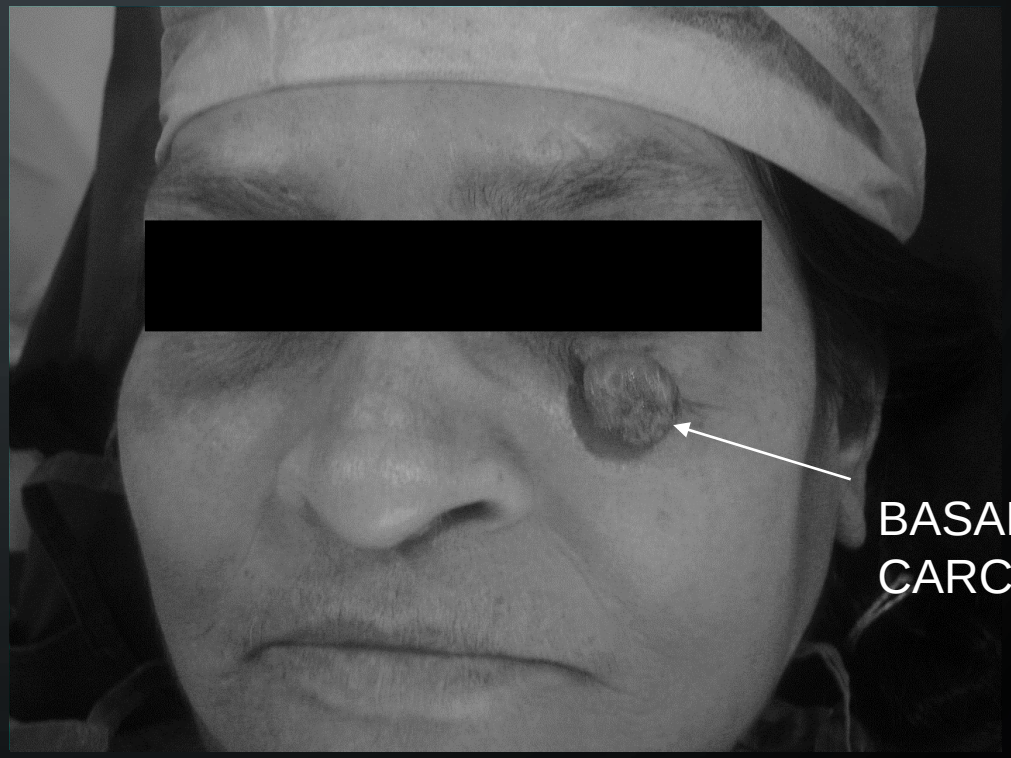


USING AN EXCEL SHEET COMPARISON OF SPECIFICITY & SENSITIVITY OF DIFF DIAGNOSTIC MODALITIES IN SCRUB TYPHUS

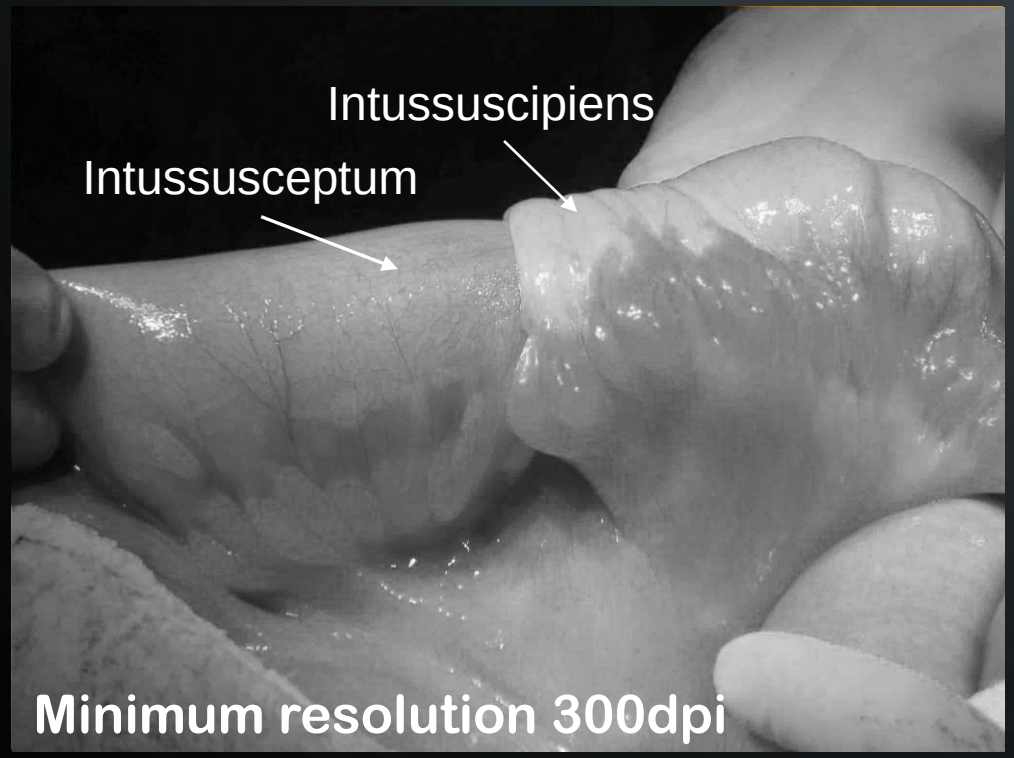


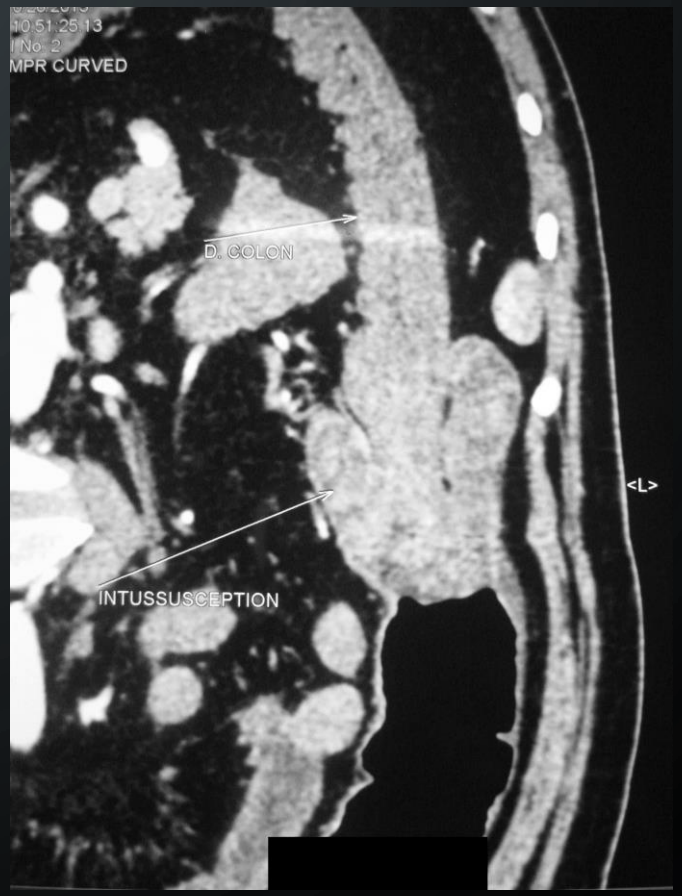
FIGURES AND DIAGRAMS

- Figures should be clear, cropped, without borders, mask clinical pictures, usually arrow marked, inscripted contrast colour labelling.
- MUST carry a written consent from the patient.



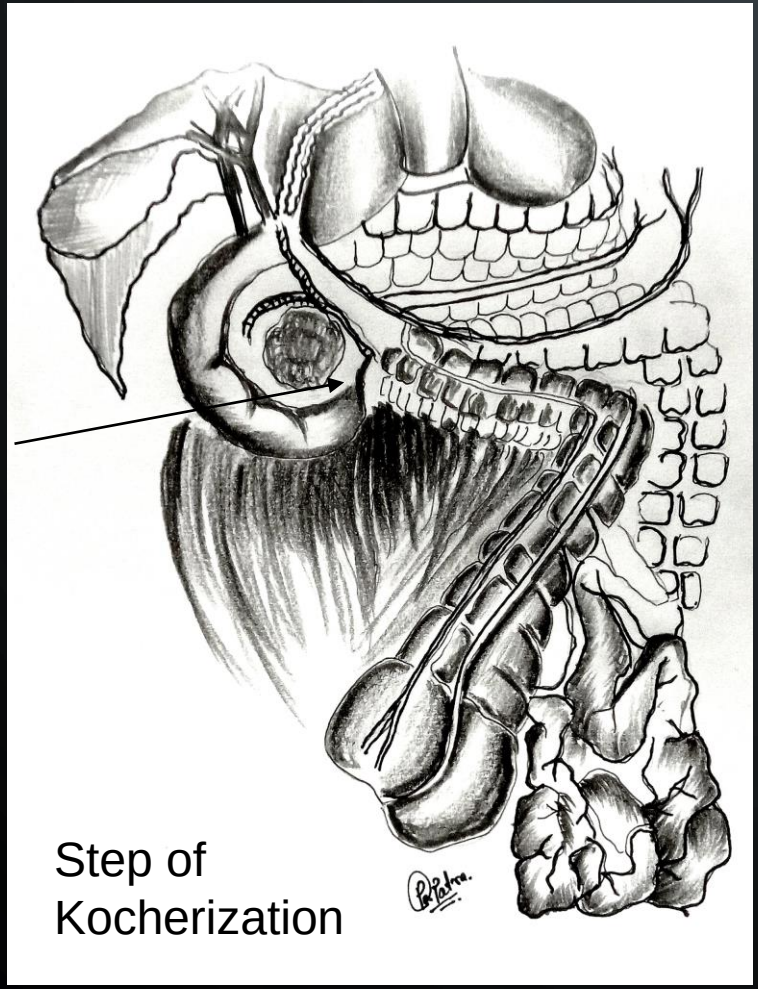
FIGURES AND DIAGRAMS



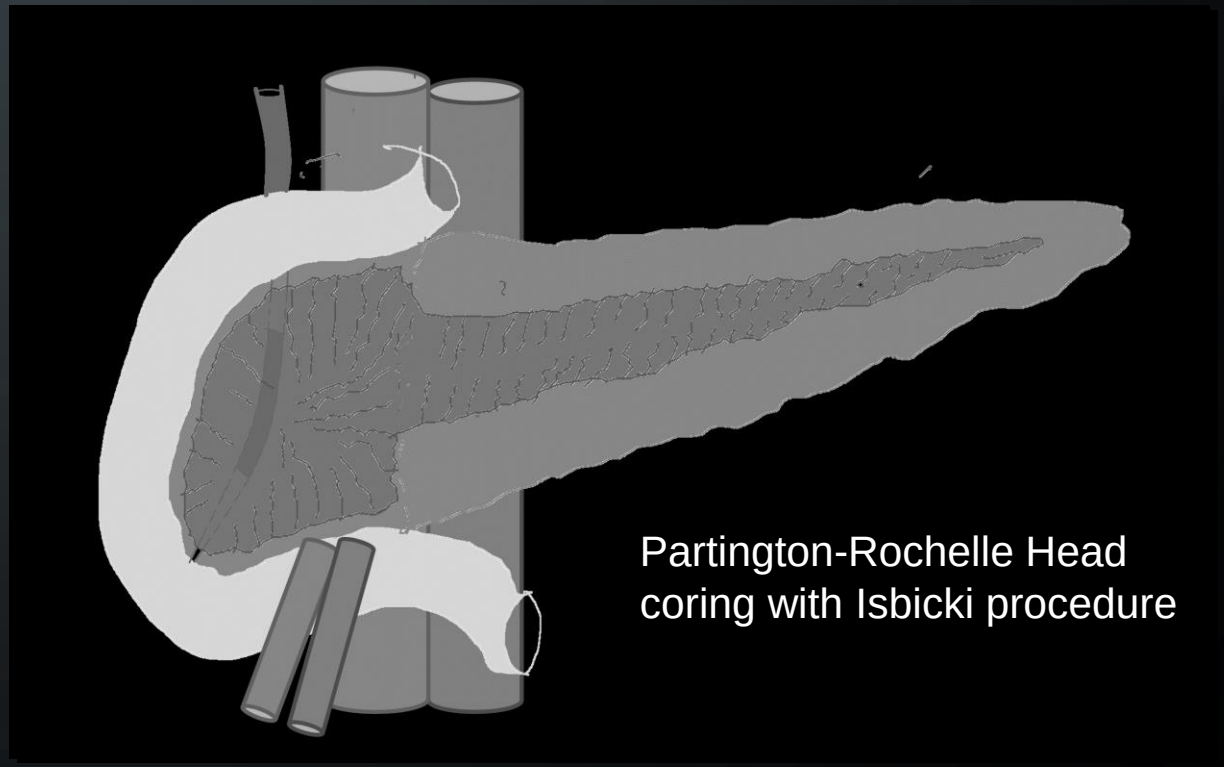


FIGURES AND DIAGRAMS

Gastro-colic trunk of Henle



Step of Kocherization



Partington-Rochelle Head coring with Isbicki procedure

STEP V INTERIOR DECORATIONS – THE MEASUREMENTS

STATISTICAL TESTS USED WITH ALL RELEVANT PARAMETERS

- FOR NORMALLY DISTRIBUTED DATA
- Means and Standard Deviations to report normally distributed data.

STATISTICAL TESTS USED WITH ALL RELEVANT PARAMETERS

- FOR SKEWED DATA
- Medians and Interpercentile ranges
- Statistically significance the ONLY thing significant.
- Reporting *p* value
  - p=0.0045 NOT
  - $p < 0.05$

MEDICAL STATISTICS

COMPLIMENTS TO:-

DR. VIVEK CHANDEL

SURGICAL GASTROENTEROLOGIST, JALANDAR

WAS DNB POST DOCTORAL TRAINEE

AT CMRI

DNB (Surgical Gastroenterology), MS (General Surgery), FIAGES G.I. Onco Surgeon & Advanced Laparoscopic Surgeon

- A love of statistics is, oddly, not what attracts most young people to a career in medicine and I suspect that many clinicians, like me, have at best a sketchy and incomplete understanding of this difficult subject.

- You wouldn't buy a car or a house without asking some questions about it first. So don't go buying into someone else's data without asking questions, either.
- Okay, you're saying... but with data there are no tires to kick, no doors to slam, no basement walls to check for water damage. Just numbers, graphs and other scary statistical things that are causing you to have bad flashbacks to your last income tax return. What the heck can you ask about data?
- Plenty. Here are a few standard questions you should ask any human beings who slap a pile of data in front of you and ask you write about it.

WHERE DID THE DATA COME FROM?

- Always ask this one first.
- An identifiable source- NEXT
- Some extra questions: A medical study on the effects of secondhand smoking- if you knew it came from a bunch of researchers employed by a tobacco company instead of from, say, a team of research physicians from a major medical school, for example.
- But, Just because a report comes from a group with a vested interest in its results doesn't guarantee the report is a sham. But you should always be extra skeptical when looking at research generated by people with a political agenda. Plenty of incentive NOT to tell you about data they found that contradict their organization's position.

HAVE THE DATA BEEN PEER-REVIEWED

- Major studies that appear in journals like the New England Journal of Medicine undergo a process called "peer review" before they are published. That means that professionals - doctors, statisticians, etc. - have looked at the study before it was published and concluded that the study's authors pretty much followed the rules of good scientific research and didn't torture their data like a middle ages infidel to make the numbers conform to their conclusions.
- Always ask if research was formally peer reviewed. If it was, you know that the data you'll be looking at are at least minimally reliable.
- And if it wasn't peer-reviewed, ask why.

HOW WERE THE DATA COLLECTED?

- If the data come from a survey, for example, you want to know that the people who responded to the survey were selected at random.
  - "self-selected sample."
  - "cherry-picking."
- Be on the lookout for cherry-picking, for example, in epidemiological studies looking at illnesses in areas surrounding toxic-waste dumps, power lines, high school cafeterias, etc. It is all too easy for a lazy researcher to draw the boundaries of the area he or she is looking at to include several extra cases of the illness in question and exclude many healthy individuals in the same area.
- When in doubt, plot the subjects of a study on map and look for yourself to see if the boundaries make sense.

BE SKEPTICAL WHEN DEALING WITH COMPARISONS.

- Researchers like to do something called a "regression," a process that compares one thing to another to see if they are statistically related. They will call such a relationship a "correlation." Always remember that a correlation DOES NOT mean causation.
- A study might find that an increase in the local birth rate was correlated with the annual migration of storks over the town. This does not mean that the storks brought the babies. Or that the babies brought the storks.
- Statisticians call this sort of thing a "spurious correlation," which is a fancy term for "total coincidence.“

FINALLY, BE AWARE OF NUMBERS TAKEN OUT OF CONTEXT.

- Again, data that are "cherry picked" to look interesting might mean something else entirely once it is placed in a different context.
- Consider the following example from Eric Meyer, a professional reporter now working at the University of Illinois:
- My personal favorite was a habit we use to have years ago, when I was working in Milwaukee. Whenever it snowed heavily, we'd call the sheriff's office, which was responsible for patrolling the freeways, and ask how many RTAs had been reported that day. Inevitably, we'd have a lead that said something like, "A fierce winter storm dumped 8 inches of snow on Milwaukee, snarled rush-hour traffic and caused 28 RTAs on county freeways" -- until one day I dared to ask the sheriff's department how many RTAs were reported on clear, sunny days. The answer -- 48 -- made me wonder whether in the future we'd run stories saying, "A fierce winter snowstorm prevented 20 RTAs on county freeways today." There may or may not have been more accidents per mile traveled in the snow, but clearly there were fewer accidents when it snowed than when it did not.
- So, look at data with a more critical attitude. (That's critical, not cynical. There is a great deal of excellent data out there.)
- The worst thing you can do as a writer is to pass along someone else's word about data without any idea whether that person's worth believing or not.

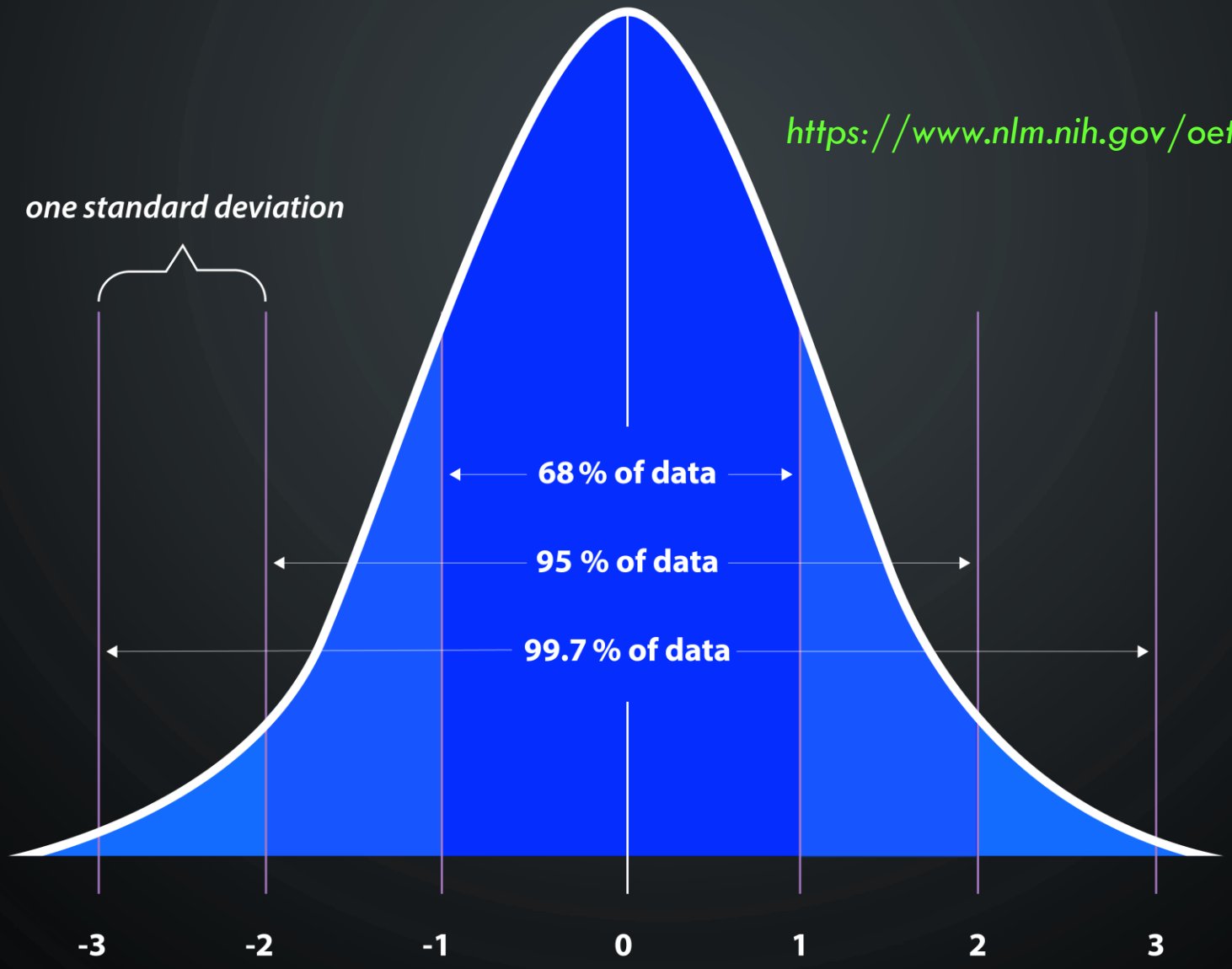
TERMINOLOGIES USED IN MEDICAL STATS

PERCENTAGES

- Percentages are mainly used in the tabulation of data in order to give the reader a scale on which to assess or compare the data.
- To calculate a percentage, divide the number of items or patients in the category by the total number in the group and multiply by 100.
- Authors can use percentages to hide the true size of the data. To say that 50% of a sample has a certain condition when there are only four people in the sample is clearly not providing the same level of information as 50% of a sample based on 400 people. So, percentages should be used as an additional help for the reader rather than replacing the actual data.

MEAN

- It is used when the spread of the data is fairly similar on each side of the mid point, for example when the data are “normally distributed”.
- The “normal distribution” is referred to a lot in statistics. It’s the symmetrical, bell-shaped distribution of data shown in next figure.



Normal distribution Curve & Standard Deviation

Five women in a study on lipid-lowering agents are aged 52, 55, 56, 58 and 59 years.

Add these ages together: 52 + 55 + 56 + 58 + 59 = 280
Now divide by the number of women: 280 /5= 56

So the mean age is 56 years.

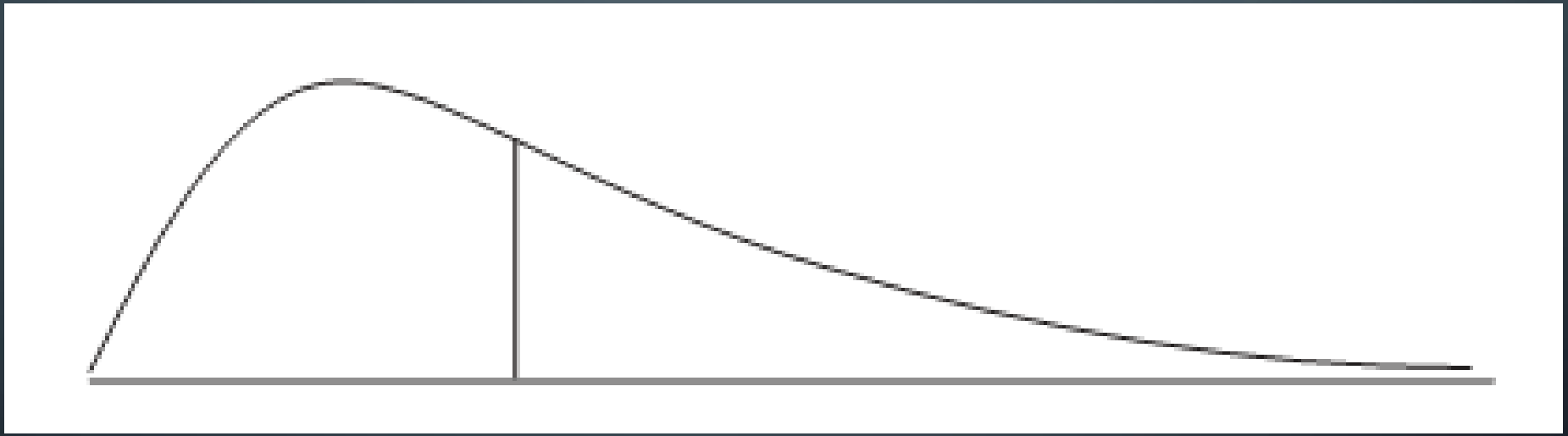
Drawback:

- If a value (or a number of values) is a lot smaller or larger than the others, “skewing” the data, the mean will then not give a good picture of the typical value.
- For example, if there is a sixth patient aged 92 in the study then the mean age would be 62, even though only one woman is over 60 years old. In this case, the “median” may be a more suitable mid-point to use.

MEDIAN

- Sometimes known as the mid-point.
- It is the point which has half the values above, and half below.
- It is used to represent the average when the data are not symmetrical, for instance the “skewed” distribution in next figure.

SKEWED DISTRIBUTION

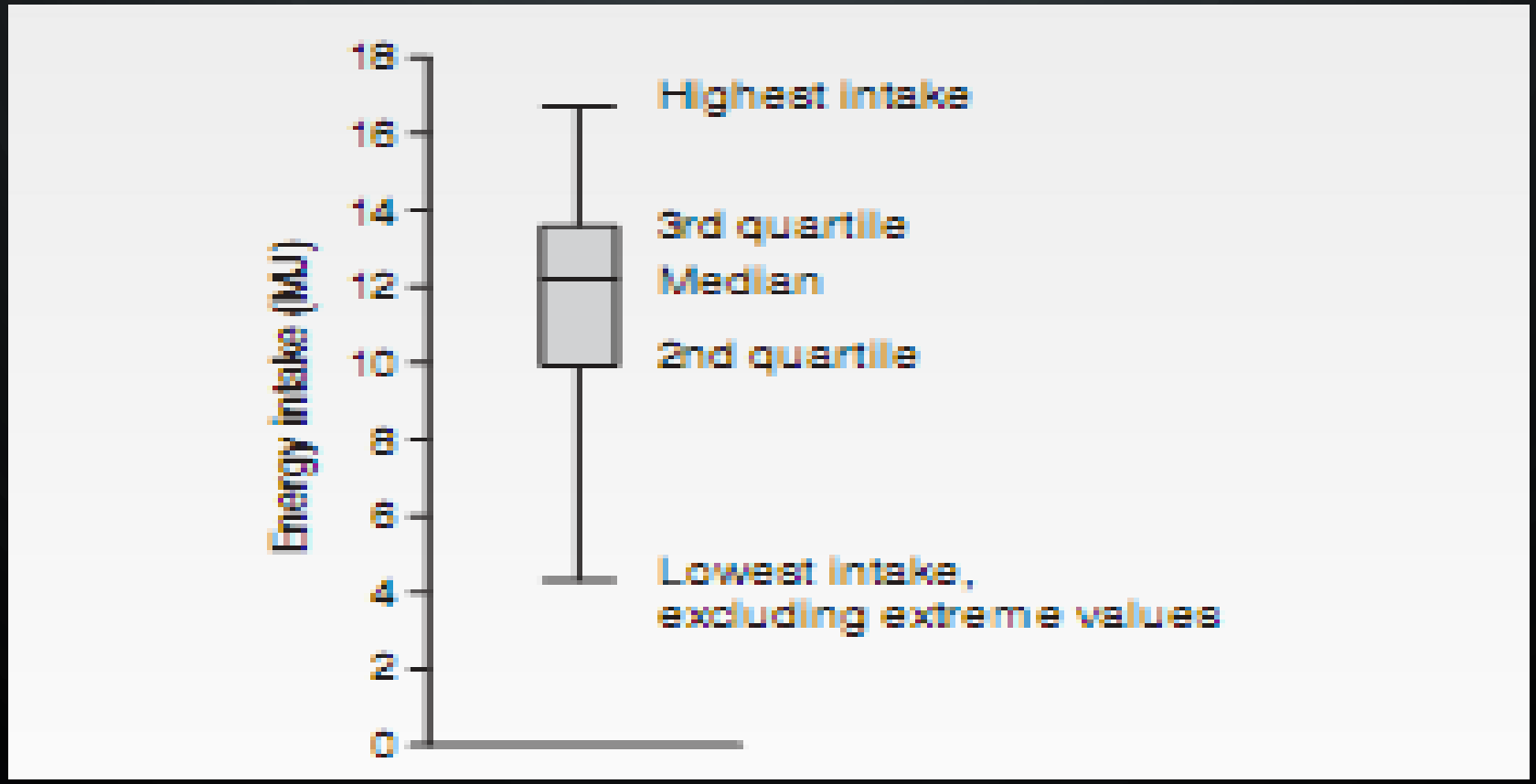


A SKEWED DISTRIBUTION CURVE.

THE CENTRAL LINE IS THE MEDIAN.

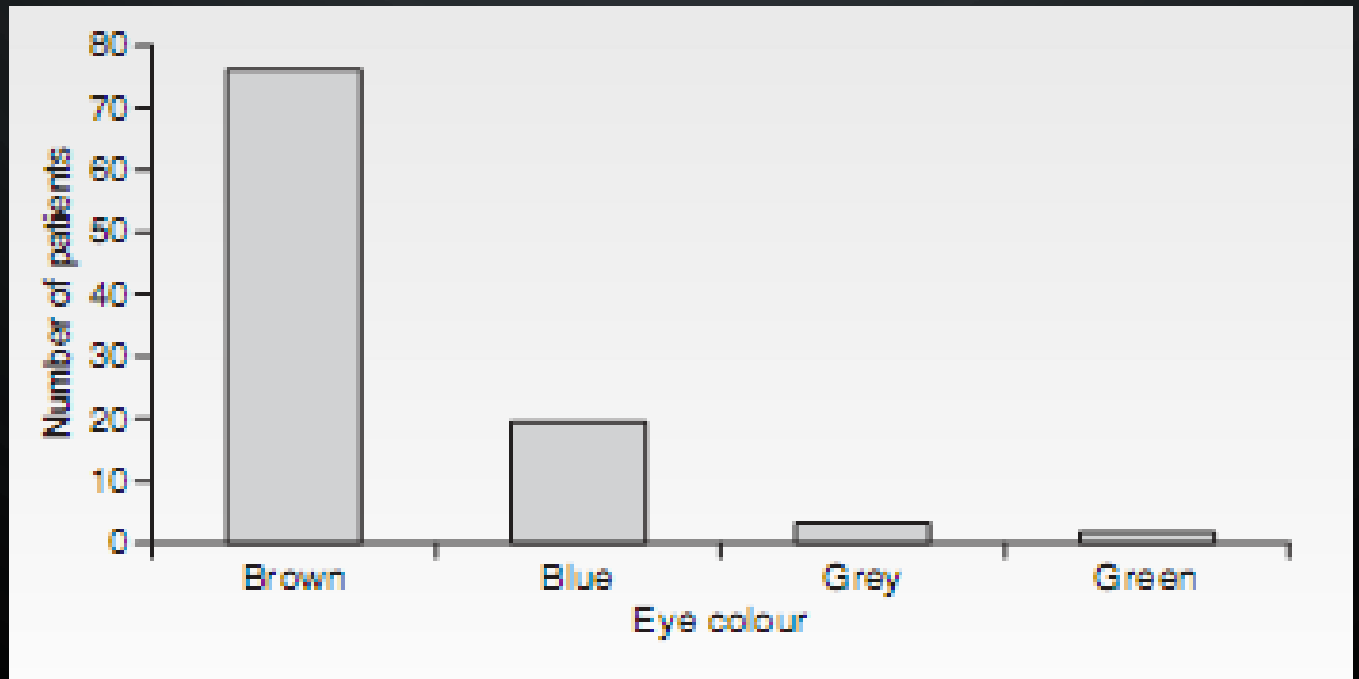
- Using the previous example from mean of five patients aged 52, 55, 56, 58 and 59, the median age is 56, the same as the mean – half the women are older, half are younger.
- However, in the second example with six patients aged 52, 55, 56, 58, 59 and 92 years, there are two “middle” ages, 56 and 58. The median is half- way between these, i.e. 57 years. This gives a better idea of the mid-point of this skewed data than the mean of 62.
- The median may be given with its inter-quartile range (IQR). The 1st quartile point has the 1/4 of the data below it, the 3rd quartile has the 3/4 of the sample below it, so the IQR contains the middle 1/2 of the sample. This can be shown in a **“box and whisker”** plot.

A dietician measured the energy intake over 24hrs of 50 pts on a variety of wards. One ward had 2 pts that were NPO. The median was 12.2 mj. Iqr 9.9 to 13.6. The lowest intake was 0, the highest was 16.7. This distribution is represented by the BOX and WHISKER plot. The ends the whiskers represent the max and minimum values, excluding extreme results.

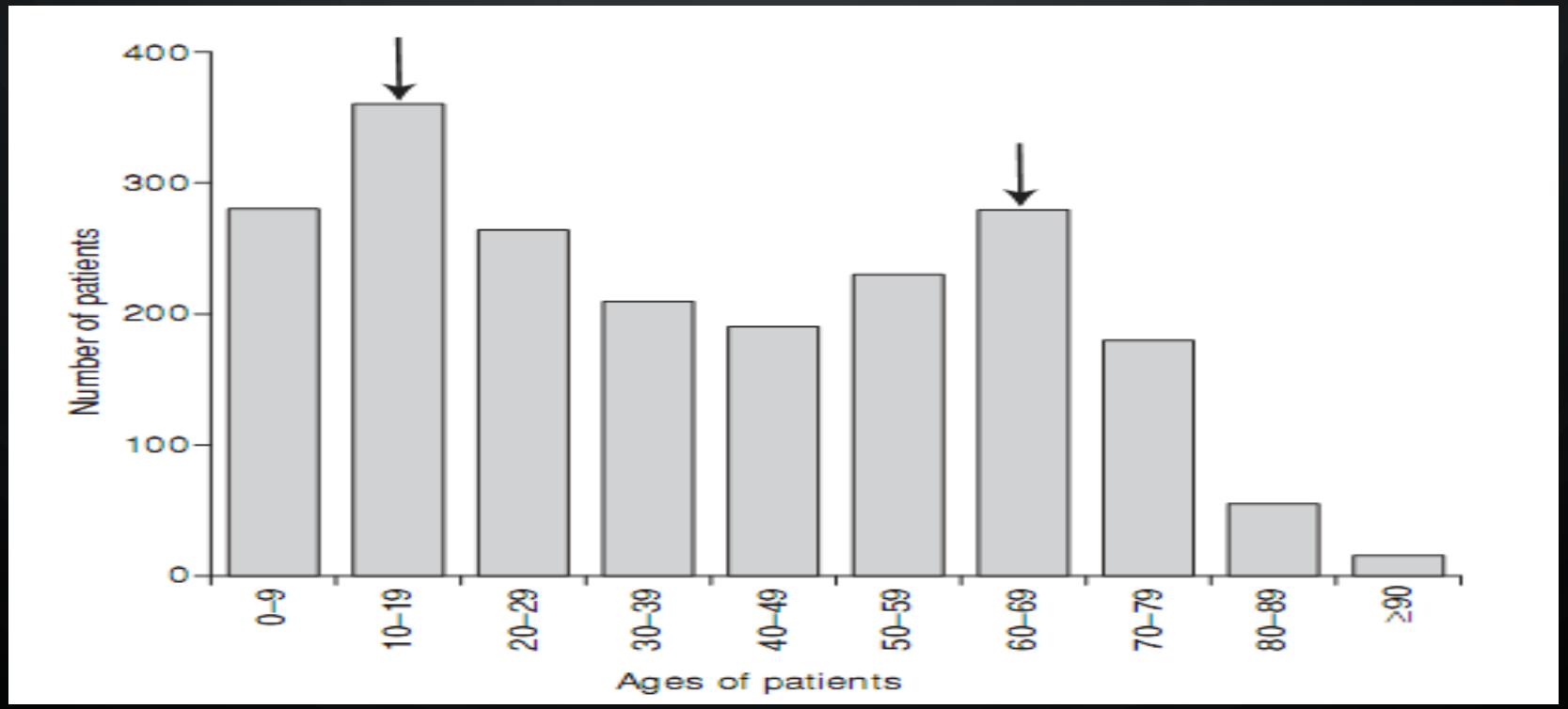


MODE

- The mode is the most common of a set of events.
- An eye clinic sister noted the eye color of 100 consecutive pts. The results are shown in figure given below.
- In this case the Mode is Brown, the commonest eye color.



You may see reference to a “**Bi-modal distribution**”. Generally when this is mentioned in papers it is as a concept rather than from calculating the actual values, e.g. “The data appear to follow a bi-modal distribution”. See *Fig. for an example of where there are two “peaks” to the data, i.e. a bi-modal distribution.*



- The arrows point to the modes at ages 10–19 and 60–69.
- Bi-modal data may suggest that two populations are present that are mixed together, so an average is not a suitable measure for the distribution.

STANDARD DEVIATION

- Standard deviation (SD) is used for data which are “normally distributed” to provide information on how much the data vary around their mean.
- SD indicates how much a set of values is spread around the average.
- A range of one SD above and below the mean (abbreviated to ± 1 SD) includes 68.2% of the values.
- ±2 SD includes 95.4% of the data.
- ±3 SD includes 99.7%.

Let us say that a group of patients enrolling for a trial had a normal distribution for weight. The mean weight of the patients was 80 kg. For this group, the SD was calculated to be 5 kg.

1 SD below the average is 80 – 5 = 75 kg.

1 SD above the average is 80 + 5 = 85 kg.

±1 SD will include 68.2% of the subjects, so 68.2% of patients will weigh between 75 and 85 kg.

95.4% will weigh between 70 and 90 kg (±2 SD).

99.7% of patients will weigh between 65 and 95 kg (±3 SD).

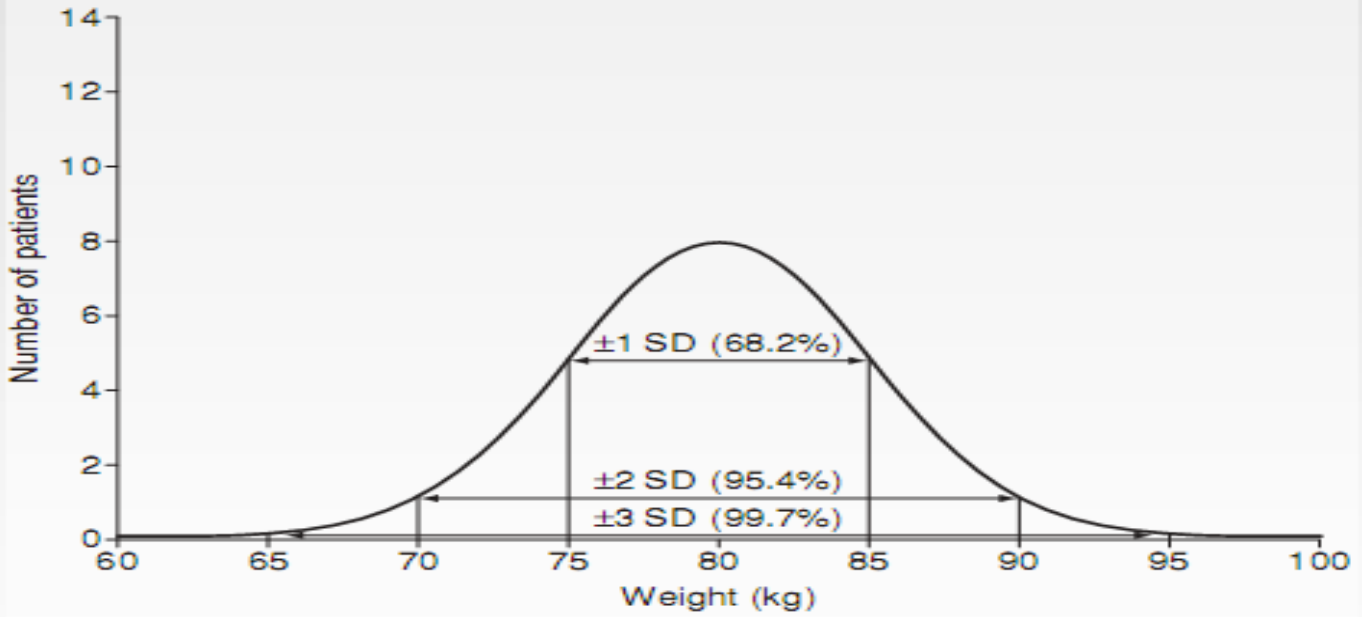


Fig. 6. Graph showing normal distribution of weights of patients enrolling in a trial with mean 80 kg, SD 5 kg.

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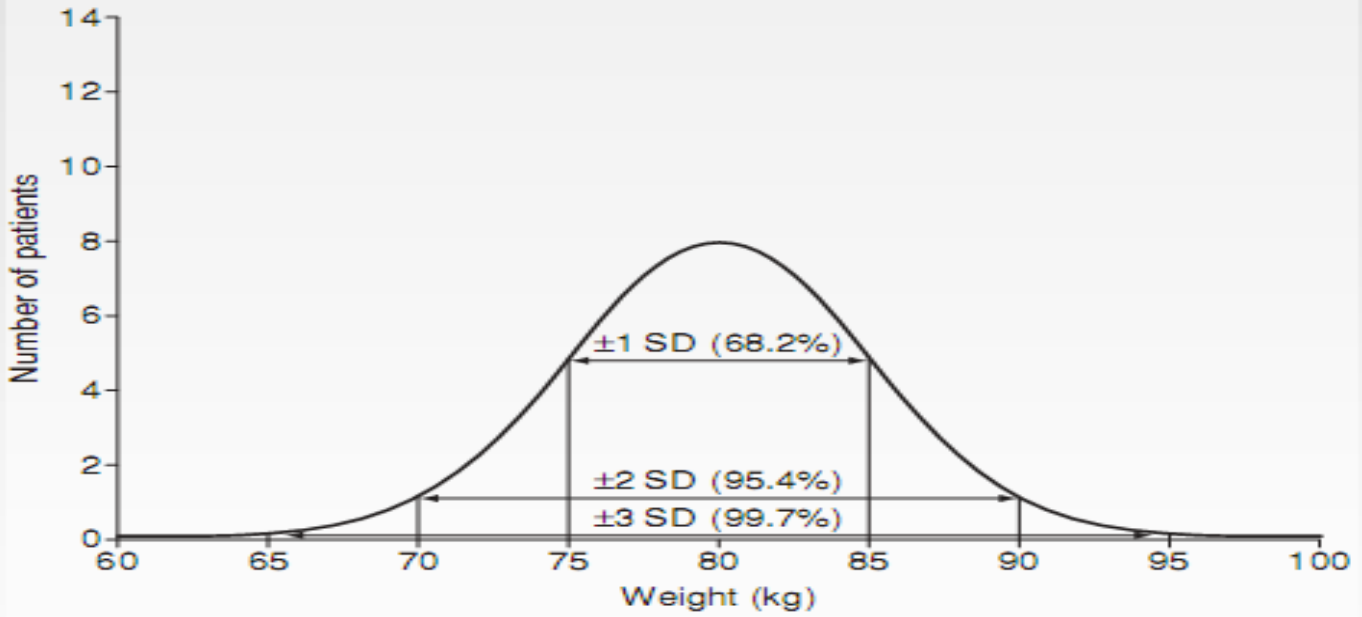


Fig. 6. Graph showing normal distribution of weights of patients enrolling in a trial with mean 80 kg, SD 5 kg.

IF WE HAVE TWO SETS OF DATA WITH THE SAME MEAN BUT DIFFERENT SDS, THEN THE DATA SET WITH THE LARGER SD HAS A WIDER SPREAD THAN THE DATA SET WITH THE SMALLER SD.
FOR EXAMPLE, IF ANOTHER GROUP OF PATIENTS ENROLLING FOR THE TRIAL HAS THE SAME MEAN WEIGHT OF 80 KG BUT AN SD OF ONLY 3, ±1 SD WILL INCLUDE 68.2% OF THE SUBJECTS, SO 68.2% OF PATIENTS WILL WEIGH BETWEEN 77 AND 83 KG

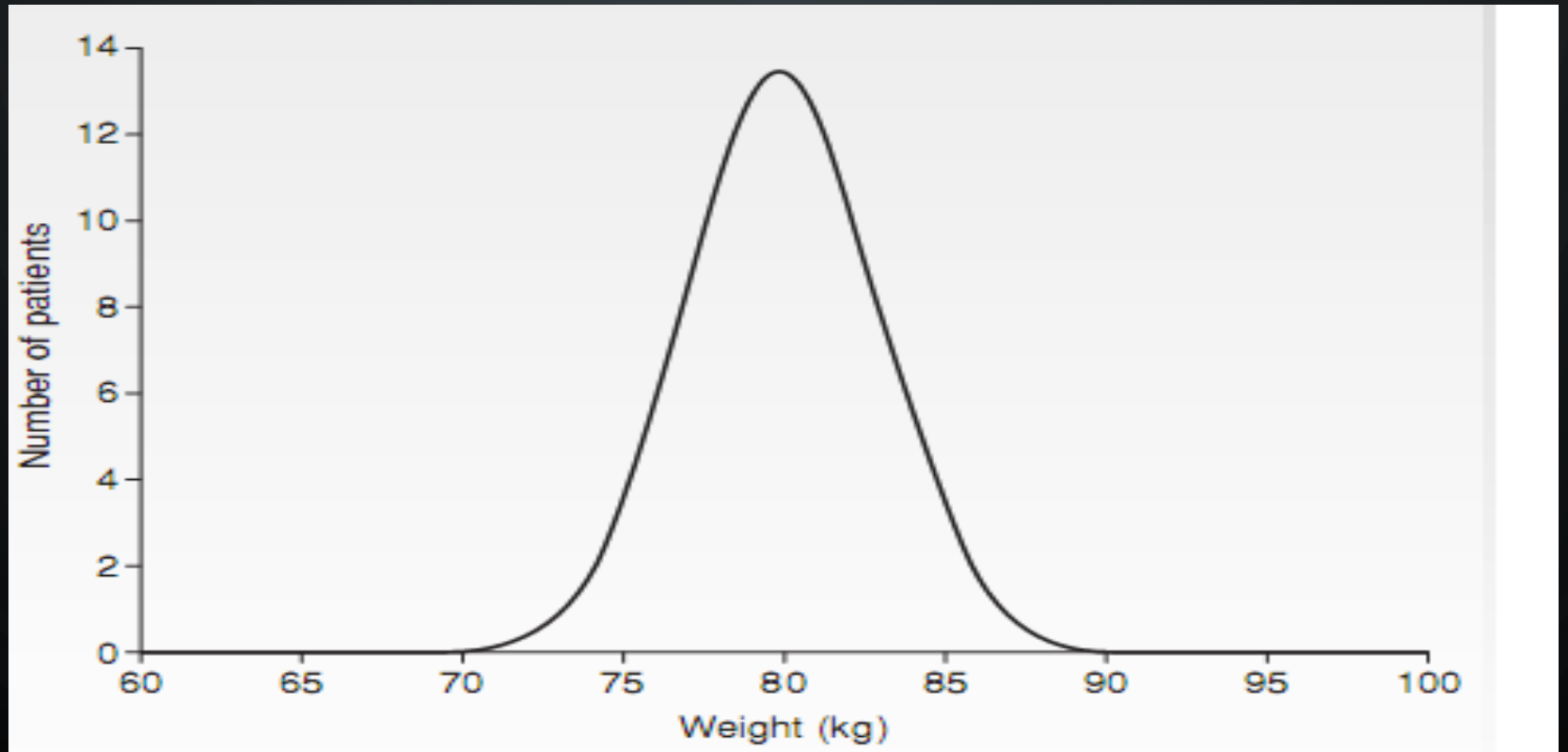


Fig. 7. Graph showing normal distribution of weights of patients enrolling in a trial with mean 80 kg, SD 3 kg.

- SD should only be used when the data have a normal distribution. However, means and SDs are often wrongly used for data which are not normally distributed.
- A simple check for a normal distribution is to see if 2 SDs away from the mean are still within the possible range for the variable. For example, if we have some length of hospital stay data with a mean stay of 10 days and a SD of 8 days then: Mean – (2 × SD) = 10 – (2 × 8) = 10 – 16 =-6 days. This is clearly an impossible value for length of stay, so the data cannot be normally distributed. The mean and SDs are therefore not appropriate measures to use.

Remember-

- ±1 SD includes 68.2% of the data
- ±2 SD includes 95.4%,
- ±3 SD includes 99.7%.

SENSITIVITY, SPECIFICITY AND PREDICTIVE VALUE

- They are used to analyze the value of screening tests.
- Think of any screening test for a disease. For each patient:
  - the disease itself may be present or absent;
  - the test result may be positive or negative.
- The results can be put in the “two-way table” shown.

		Disease:	
		Present	Absent
Test result:	Positive	A	B (False positive)
	Negative	C (False negative)	D

SENSITIVITY. IF A PATIENT HAS THE DISEASE, WE NEED TO KNOW HOW OFTEN THE TEST WILL BE POSITIVE, I.E. “POSITIVE IN DISEASE”.

THIS IS CALCULATED FROM: A/ A+C.

THIS IS THE RATE OF PICK-UP OF THE DISEASE IN A TEST, AND IS CALLED THE *SENSITIVITY.*

SPECIFICITY. IF THE PATIENT IS IN FACT HEALTHY, WE WANT TO KNOW HOW OFTEN THE TEST WILL BE NEGATIVE, I.E. “NEGATIVE IN HEALTH”.

THIS IS GIVEN BY: D/D+B

THIS IS THE RATE AT WHICH A TEST CAN EXCLUDE THE POSSIBILITY OF THE DISEASE, AND IS KNOWN AS THE S*PECIFICITY.*

- **Positive Predictive Value**. If the test result is positive, what is the likelihood that the patient will have the condition?
  - Look at: A/A+B.
  - This is known as the *Positive Predictive Value (PPV).*
- **Negative Predictive Value.** If the test result is negative, what is the likelihood that the patient will be healthy?
  - Here we use: D/D+C.
  - This is known as the *Negative Predictive Value(NPV).*
- *In a perfect test, the sensitivity, specificity, PPV and* NPV would each have a value of 1. The lower the value (the nearer to zero), the less useful the test is in that respect.

- Imagine a blood test for gastric cancer, tried out on 100 patients admitted with haematemesis. The actual presence or absence of gastric cancers was diagnosed from endoscopic findings and biopsy. The results are shown in *Table.*

Blood result	Gastric cancer	
	Present	Absent
Positive	20 (TP)	30 (FP)
Negative	5 (FN)	45 (TN)

- *Sensitivity- 20/ 20+5= 0.8*
- *Specificity- 45/30+45= 0.6*
- If there is no gastric cancer there is a 60% (0.6) chance of the test being negative – but 40% will have a false positive result.

- PPV- 20/ 20+30= 0.4
- There is a 40% (0.4) chance, if the test is positive, that the patient actually has gastric cancer.
- PPV- 45/ 45+5= 0.9
- There is a 90% (0.9) chance, if the test is negative, that the patient does not have gastric cancer. However, there is still a 10% chance of a false negative, i.e. that the patient does have gastric cancer.

- One more test to know about. The **"Likelihood Ratio" (LR)"** is the likelihood that the test result would be expected in a patient with the condition compared to the likelihood that that same result would be expected in a patient without the condition.
- To calculate the LR, divide the sensitivity by (1 – specificity).

Two-way table for blood test for gastric cancer

$$\text{LR} = \frac{\text{sensitivity}}{(1 - \text{specificity})} = \frac{0.8}{1 - 0.6} = \frac{0.8}{0.4} = 2$$

- In this example, LR for a positive result = 2. This means that if the test is positive in a patient, that patient is twice as likely to have gastric cancer than not have it.

- **Sensitivity:** how often the test is positive if the patient has the disease.
- **Specificity:** if the patient is healthy, how often the test will be negative.
- **PPV:** If the test is positive, the likelihood that the patient has the condition.
- **NPV:** If the test is negative, the likelihood that the patient will be healthy.
- **LR:** If the test is positive, how much more likely the patient is to have the disease than not have it.

CONFIDENCE INTERVALS

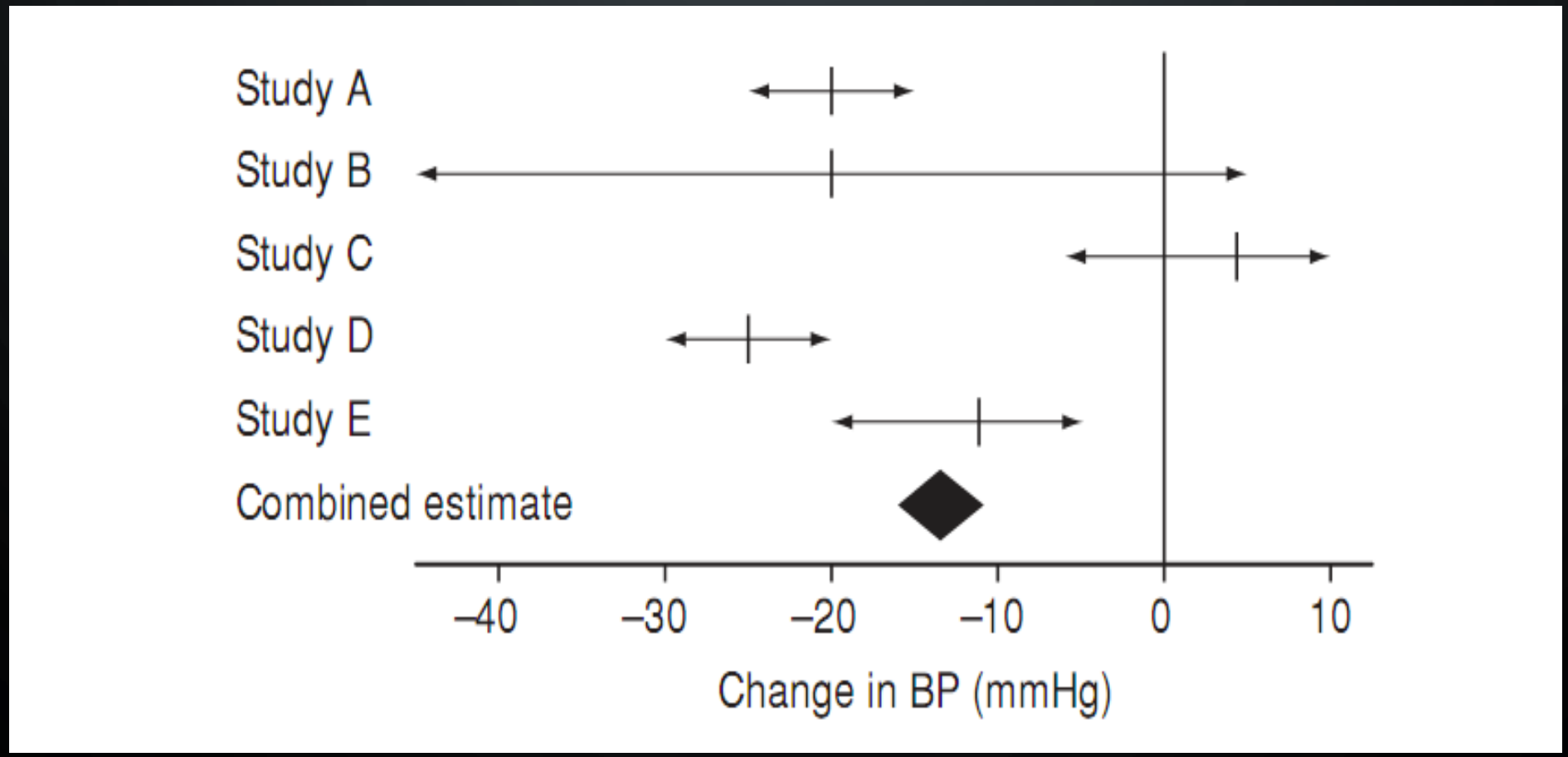
- Confidence intervals (CI) are typically used when, instead of simply wanting the mean value of a sample, we want a range that is likely to contain the true population value.
- This “true value” is another tough concept – it is the mean value that we would get if we had data for the whole population.
- Statisticians can calculate a range (interval) in which we can be fairly sure (confident) that the “true value” lies.

- For example, we may be interested in blood pressure (BP) reduction with antihypertensive treatment. From a sample of treated patients we can work out the mean change in BP.
- However, this will only be the mean for our particular sample. If we took another group of patients we would not expect to get exactly the same value, because chance can also affect the change in BP.
- The CI gives the range in which the true value (i.e. the mean change in BP if we treated an infinite number of patients) is likely to be.

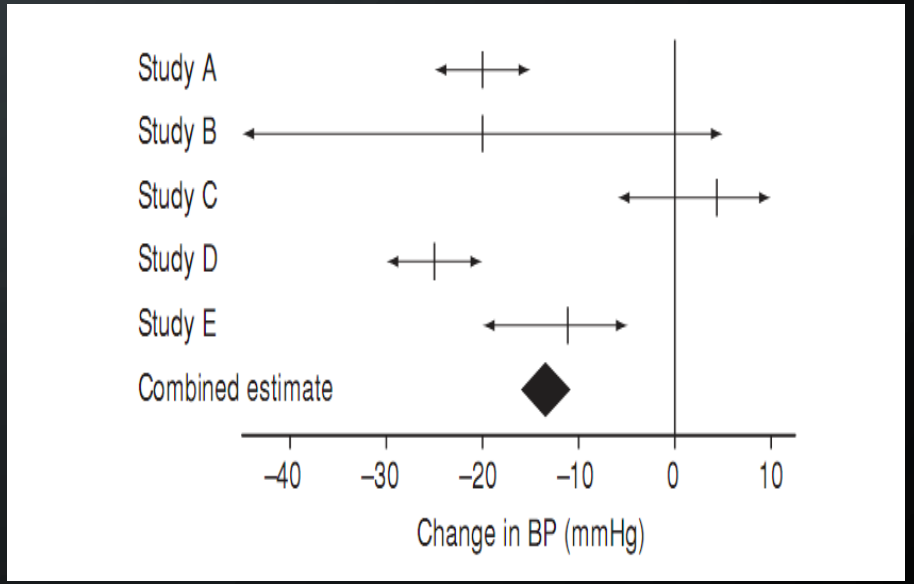
- The average systolic BP before treatment in study A, of a group of 100 hypertensive patients, was 170 mmHg. After treatment with the new drug the mean BP dropped by 20 mmHg.
- If the 95% CI is 15–25, this means we can be 95% confident that the true effect of treatment is to lower the BP by 15–25 mmHg.
- In study B 50 patients were treated with the same drug, also reducing their mean BP by 20 mmHg, but with a wider 95% CI of -5 to +45. This CI includes zero (no change). This means there is more than a 5% chance that there was no true change in BP, and that the drug was actually ineffective.

- The size of a CI is related to the sample size of the study. **Larger studies usually have a narrower CI**.
- Where a few interventions, outcomes or studies are given it is difficult to visualize a long list of means and CIs. Some papers will show a chart to make it easier.
- For example, "**meta-analysis**" is a technique for bringing together results from a number of similar studies to give one overall estimate of effect. Many meta-analyses compare the treatment effects from those studies by showing the mean changes and 95% CIs in a chart.

PLOT OF 5 STUDIES OF A NEW ANTIHYPERTENSIVE DRUG. SEE HOW THE RESULTS OF STUDIES A AND B ARE SHOWN BY THE TOP TWO LINES, I.E. 20 mmHg, 95% CI 15-25 FOR STUDY A AND 20 mmHg, 95% CI -5 TO +45 FOR STUDY B



- The vertical axis does not have a scale. It is simply used to show the zero point on each CI line.
- The statistician has combined the results of all five studies and calculated that the overall mean reduction in BP is 14 mmHg, CI 12–16. This is shown by the "combined estimate" diamond.
- See how combining a number of studies reduces the CI, giving a more accurate estimate of the true treatment effect.
- The chart shown *is called a "Forest plot" or, more colloquially, a "blobbogram".*
- **Standard deviation and confidence intervals – what is the difference?**
  - Standard deviation tells us about the variability (spread) in a sample.
  - The CI tells us the range in which the true value (the mean if the sample were infinitely large) is likely to be.

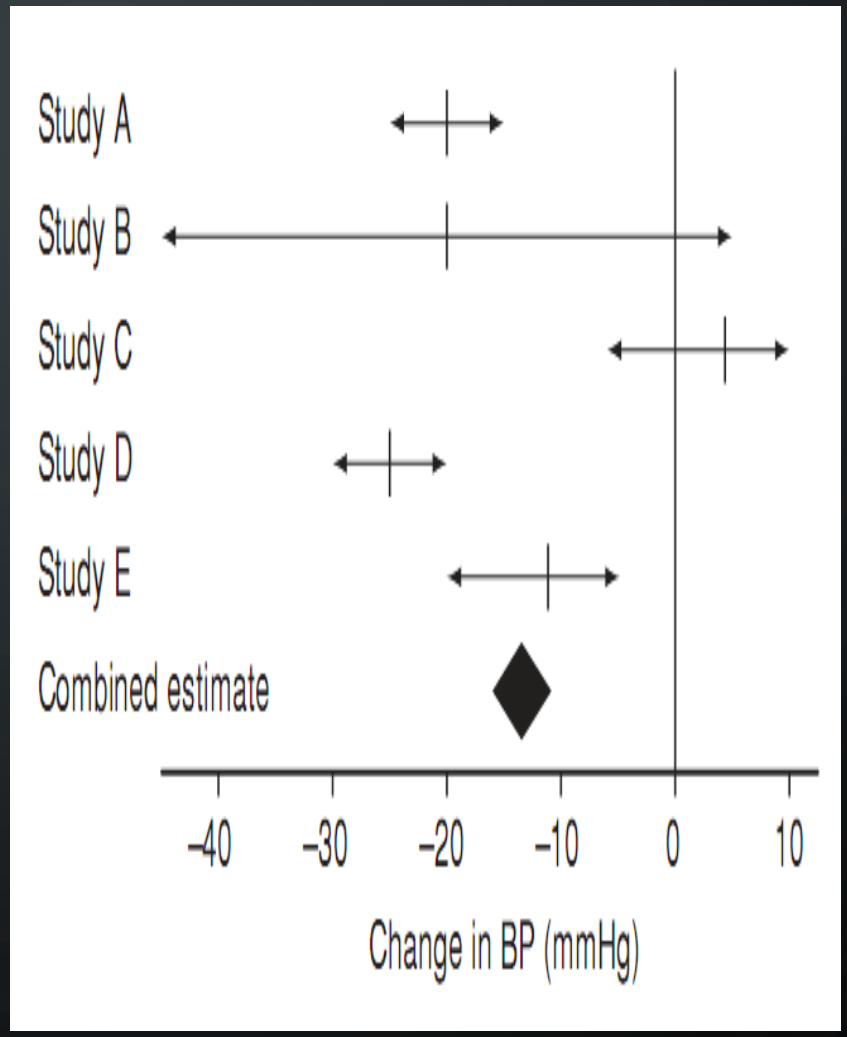


- Which study showed the greatest change?
- Did all the studies show change in favour of the intervention?
- Were the changes statistically significant?

In the example above, study D showed the greatest change, with a mean BP drop of 25 mmHg.

Study C resulted in a mean increase in BP, though with a wide CI. The wide CI could be due to a low number of patients in the study.

The combined estimate of a mean BP reduction of 14 mmHg, 95% CI 12–16, is statistically significant.



P VALUES

- The *P (probability) value is used when we wish to see how likely it is that a hypothesis is true. The hypothesis is usually that there is no difference between two treatments, known as the "null hypothesis".*
- The *P value gives the probability of any observed difference having happened by chance.*
- *P = 0.5 means that the probability of the difference having happened by chance is 0.5 in 1, or 50:50.*
- *P = 0.05 means that the probability of the difference having happened by chance is 0.05 in 1, i.e. 1 in 20.*
- The lower the *P value, the less likely it is that the* difference happened by chance and so the higher the significance of the finding.
- *P = 0.01 is often considered to be "highly significant". It means that the difference will only have happened by chance 1 in 100 times. This is unlikely, but still possible.*

POWER

- The power of a study is the probability that it would detect a statistically significant difference.
- If the difference expected is 100% cure compared with 0% cure with previous treatments, a very small study would have sufficient power to detect that.
- However if the expected difference is much smaller, e.g. 1%, then a small study would be unlikely to have enough power to produce a result with statistical significance.

RISK RATIO
OFTEN REFERRED TO AS RELATIVE RISK.

- Relative risk is used in “cohort studies”, prospective studies that follow a group (cohort) over a period of time and investigate the effect of a treatment or risk factor.
- First, risk itself. *Risk is the probability that an event will happen. It is calculated by dividing the number of events by the number of people at risk.*
- One boy is born for every two births, so the probability (risk) of giving birth to a boy is 1/ 2 = 0.5
- If one in every 100 patients suffers a side-effect from a treatment, the risk is 1/ 100 = 0.01

- Now, risk *ratios. These are calculated by dividing the risk in the treated or exposed group by the risk in the control or unexposed group.*
- A risk ratio of one indicates no difference in risk between the groups.
- If the risk ratio of an event is >1, the rate of that event is increased compared to controls.
- If <1, the rate of that event is reduced. Risk ratios are frequently given with their 95% CIs –

  If the CI for a risk ratio *does not include one (no difference in risk), it is statistically significant.*

- A cohort of 1000 regular football players and 1000 non-footballers were followed to see if playing football was significant in the injuries that they received.
- After 1 year of follow-up there had been 12 broken legs in the football players and only 4 in non-footballers.
- The *risk of a footballer breaking a leg was therefore 12/1000 or 0.012. The risk of a non-footballer breaking a leg was 4/1000 or 0.004.*
- The risk *ratio of breaking a leg was therefore 0.012/0.004 which equals three. The 95% CI was calculated to be 0.97 to 9.41.*
- *As the CI includes the value 1 we cannot exclude the possibility that there was no difference in the risk of footballers and non-footballers breaking a leg. However, given these results further investigation would clearly be warranted.*

ATTRIBUTABLE RISK
ALSO CALLED RISK DIFFERENCE

- It is the difference in incidence rates of disease (or death) between an exposed group and Non-exposed group.
- It indicates to what extent the disease under study can be attributed to the exposure.
- AR is often expressed as a percent.

$$\frac{\text{Incidence of Ds rate among exposed- incidence of Ds rate among non-exposed}}{\text{Incidence rate among exposed}} \times 100$$

RELATIVE RISK VS ATTRIBUTABLE RISK

- Relative Risk is important in aetiological enquiries. Its size is a better index than is AR for assessing the Aetiological role of a factor in disease. The larger the risk, the stronger the association between cause and effect.
- But RR does not reflect the potential public health importance as does the AR. AR gives a better idea of the impact of successful preventive or public health programme might have in reducing the problem.

ODDS RATIO

- Used by epidemiologists in studies looking for factors which do harm, it is a way of comparing patients who already have a certain condition (cases) with patients who do not (controls) – a “case–control study”.
- First, *odds. Odds are calculated by dividing the number of times an event happens by the number of times it does not happen.*
- One boy is born for every two births, so the odds of giving birth to a boy are 1:1 (or 50:50) =1/1 = 1
- If one in every 100 patients suffers a side effect from a treatment, the odds are 1:99 = 1/99 = 0.0101
- Compare this with risk.

- Next, odds *ratios. They are calculated by dividing the odds of having been exposed to a risk factor by the odds in the control group.*
- An odds ratio of 1 indicates no difference in risk between the groups, i.e. the odds in each group are the same.
- If the odds ratio of an event is >1, the rate of that event is increased in patients who have been exposed to the risk factor.
- If <1, the rate of that event is reduced. Odds ratios are frequently given with their 95% CI –

  If the CI for an odds ratio *does not include 1 (no difference in odds), it is statistically significant.*

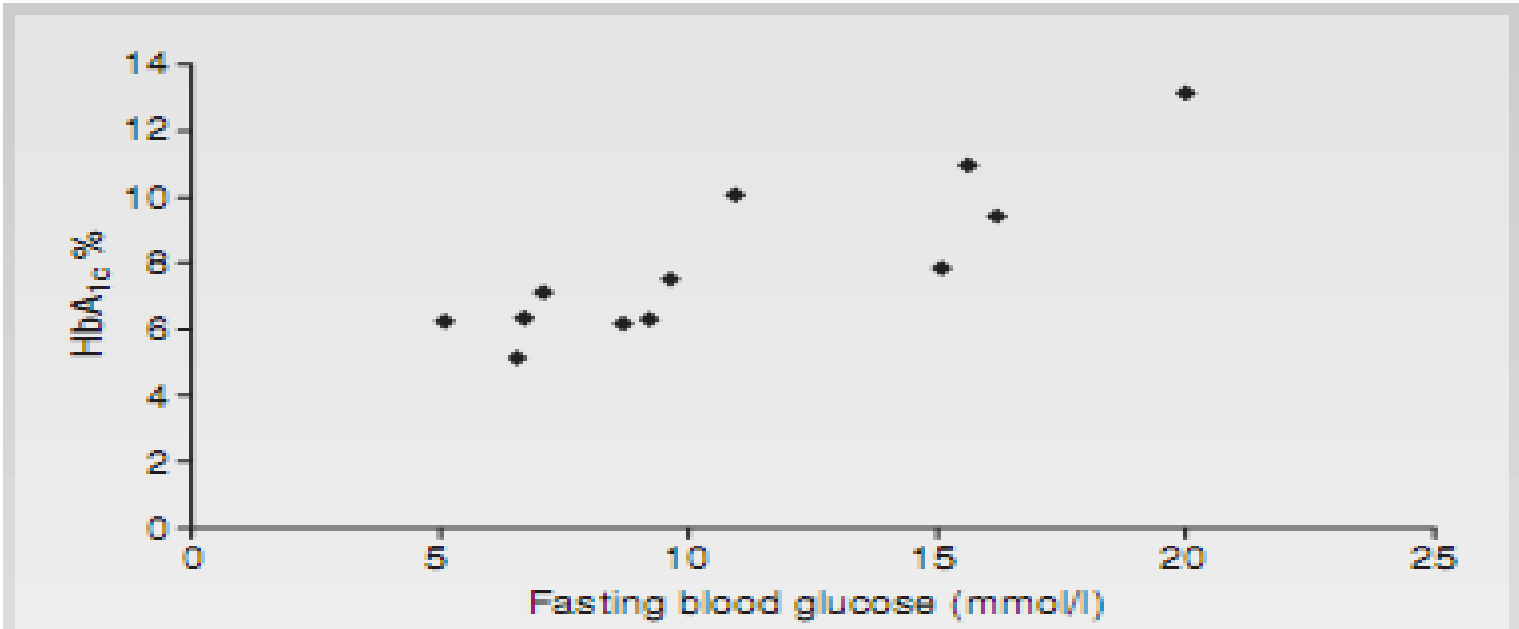
- A group of 100 patients with knee injuries, “cases”, was matched for age and sex to 100 patients who did not have injured knees, “controls”.
- In the cases, 40 skied and 60 did not, giving the *odds of being a skier for this group of 40:60 or 0.66.*
- In the controls, 20 patients skied and 80 did not, giving the odds of being a skier for the control group of 20:80 or 0.25.
- We can therefore calculate the odds *ratio as 0.66/0.25 = 2.64. The 95% CI is 1.41 to 5.02.*
- If you cannot follow the maths, do not worry! The odds ratio of 2.64 means that the number of skiers in the cases is higher than the number of skiers in the controls, and as the CI does not include 1 (no difference in risk) this is statistically significant. Therefore, we can conclude that skiers are more likely to get a knee injury than non-skiers.

- Authors may give the percentage *change in the odds ratio rather than the odds ratio itself. In the example above, the odds ratio of 2.64 means the same as a 164% increase in the odds of injured knees amongst skiers.*
- **Odds ratios are often interpreted by the reader in the same way as risk ratios. This is reasonable when the odds are low, but for common events the odds and the risks (and therefore their ratios) will give very different values.** For example, the odds of giving birth to a boy are 1, whereas the risk is 0.5. However, in the side-effect example given above the odds are 0.0101, a similar value to the risk of 0.01.
- **For this reason, if you are looking at a case–control study, check that the authors have used odds ratios rather than risk ratios.**

CORRELATION

- Linear relationship between two variables. Examples are height and weight in children, or socio-economic class and mortality.
- The *strength of that relationship is given by the "**correlation coefficient**".*
- The correlation coefficient is usually denoted by the letter "*r" for example r = 0.8*
- ***Positive correlation coefficient-** As one variable is increasing the value for the other variable is also increasing – the line on the graph slopes up from left to right. Height and weight have a positive correlation: children get heavier as they grow taller.*
- ***Negative correlation coefficient-** As the value of one variable goes up the value for the other variable goes down – the graph slopes down from left* to right. Higher socio-economic class is associated with a lower mortality, giving a negative correlation between the two variables.
- If there is a perfect relationship between the two variables then *r = 1 (if a positive correlation) or r =-1 (if a negative correlation). If there is no correlation at all (the points on the* graph are completely randomly scattered) then *r = 0.*
- Correlation tells us how strong the association between the variables is, but does not tell us about cause and effect in that relationship.

- A nurse wanted to be able to predict the laboratory HbA^{1c} result (a measure of blood glucose control) from the fasting blood glucoses which she measured in her clinic. On 12 consecutive diabetic patients she noted the fasting glucose and simultaneously drew blood for HbA^{1c}. She compared the pairs of measurements and drew the graph.



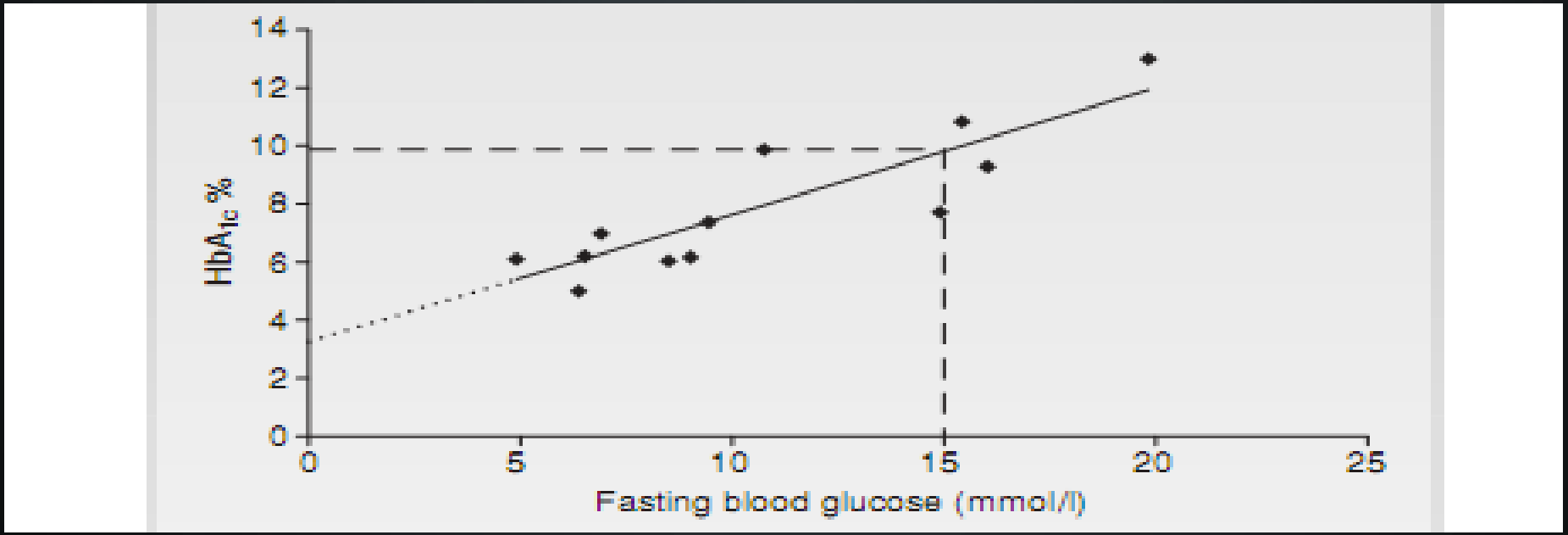
- **Plot of fasting glucose and HbA^{1c}** in 12 patients with diabetes. For these results *r = 0.88, showing a very high correlation.*

- Where the author shows the graph, you can get a good idea from the scatter as to how strong the relationship is without needing to know the *r value.*
- Authors often give *P values with correlations, however take care when interpreting them. Although a correlation needs to be significant, we need also to consider the size of the correlation. If a study is sufficiently large, even a small clinically unimportant correlation will be highly significant.*
- It is very easy for authors to compare a large number of variables using correlation and only present the ones that happen to be significant. So, check to make sure there is a plausible explanation for any significant correlations.
- Also bear in mind that a correlation only tells us about linear (straight line) relationships between variables. Two variables may be strongly related but not in a straight line, giving a low correlation coefficient.

REGRESSION

- A regression line is the “best fit” line through the data points on a graph.
- The regression coefficient gives the “slope” of the graph, in that it gives the change in value of one outcome, per unit change in the other.

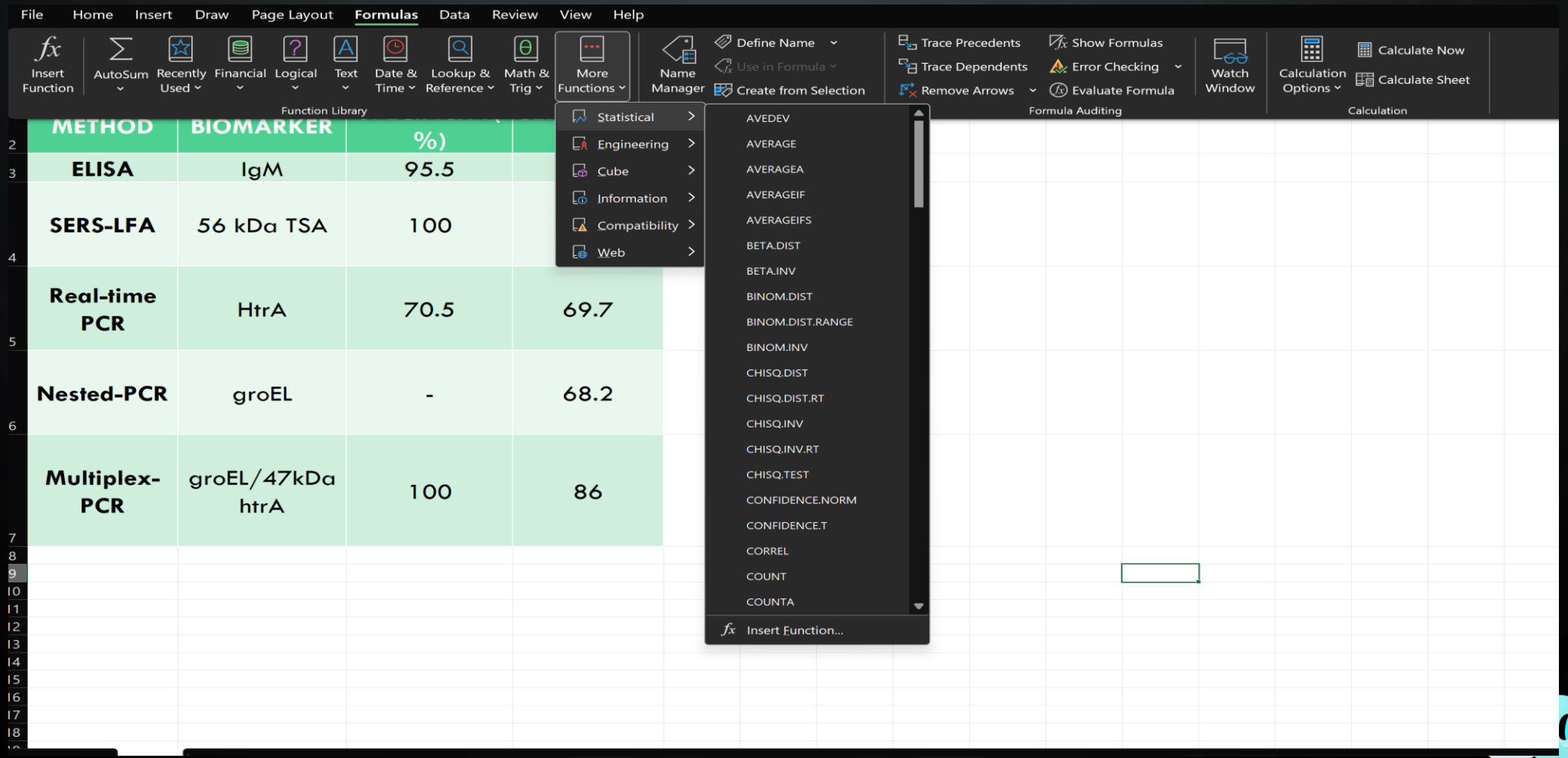
- Consider the graph. *A statistician calculated the line that gave the "best fit" through the scatter of points.*



- **Plot with linear regression line of fasting glucose and HbA** in 12 patients with diabetes.
- The line is called a "regression line". To predict the HbA1c for a given blood glucose the nurse could simply plot it on the graph, as here where a fasting glucose of 15 predicts an HbA1c of 9.95.

- Regression should not be used to make predictions outside of the range of the original data. In the example above, we can only make predictions from blood glucoses which are between 5 and 20.
- Regression and correlation are easily confused. Correlation measures the *strength of the association* between variables. Regression *quantifies the association. It should only* be used if one of the variables is thought to precede or cause the other.

USING EXCEL FOR STATS



STEP V INTERIOR DECORATIONS – THE MEASUREMENTS STATISTICAL CHECK-THE CHAMP STATEMENT

- Mansournia MA, Collins GS, Nielsen RO, Nazemipour M, Jewell NP, Altman DG, Campbell MJ. A CHecklist for statistical Assessment of Medical Papers (the CHAMP statement): explanation and elaboration. Br J Sports Med. 2021 Sep;55(18):1009-1017. doi: 10.1136/bjsports-2020-103652. Epub 2021 Jan 29. PMID: 33514558; PMCID: PMC9110112.

STEP V INTERIOR DECORATIONS – THE MEASUREMENTS STATISTICAL CHECK-THE CHAMP STATEMENT

Design and conduct				
1.	Clear description of the **goal** of research, study objective(s), study design, and study population	Yes	Unclear	No
2.	Clear description of **outcomes, exposures/treatments and covariates,** and their measurement methods	Yes	Unclear	No
3.	**Validity** of study design	Yes	Unclear	No
4.	Clear statement and justification of **sample size**	Yes	Unclear	No
5.	Clear declaration of **design violations** and acceptability of the design violations	Yes	Unclear	No

STEP V INTERIOR DECORATIONS – THE MEASUREMENTS STATISTICAL CHECK-THE CHAMP STATEMENT

Data analysis				
7.	Correct and complete description of **statistical methods**	Yes	Unclear	No
8.	**Valid statistical methods** used and assumptions outlined	Yes	Unclear	No
9.	Appropriate **assessment of treatment effect or interaction** between treatment and another covariate	Yes	Unclear	No
10.	Correct use of **correlation and association statistical testing**	Yes	Unclear	No
11.	Appropriate handling of **continuous predictors**	Yes	Unclear	No
12.	**Confidence intervals** do not include impossible values	Yes	Unclear	No
13.	Appropriate comparison of **baseline characteristics** between the study arms in randomized trials	Yes	Unclear	No
14.	Correct assessment and adjustment of **confounding**	Yes	Unclear	No
15.	**Avoiding model extrapolation** not supported by data	Yes	Unclear	No
16.	Adequate handling of **missing data**	Yes	Unclear	No

STEP V INTERIOR DECORATIONS – THE MEASUREMENTS STATISTICAL CHECK-THE CHAMP STATEMENT

Reporting and presentation				
17.	Adequate and correct description of the **data**	Yes	Unclear	No
18.	Descriptive results provided as occurrence measures with confidence intervals, and analytic results provided as **association measures and confidence intervals along with P-values**	Yes	Unclear	No
19.	**Confidence intervals** provided for the contrast between groups rather than for each group	Yes	Unclear	No
20.	Avoiding **selective reporting** of analyses and P-hacking	Yes	Unclear	No
21.	Appropriate and consistent **numerical precisions** for effect sizes, test statistics, and P-values, and reporting the P-values rather their range	Yes	Unclear	No
22.	Providing sufficient **numerical results** that could be included in a subsequent meta-analysis	Yes	Unclear	No
23.	Acceptable presentation of the **figures and tables**	Yes	Unclear	No

STEP V INTERIOR DECORATIONS – THE MEASUREMENTS STATISTICAL CHECK-THE CHAMP STATEMENT

Interpretation				
24.	Interpreting the results based on association measures and **95% confidence intervals along with P-values,** and correctly interpreting large P-values as indecisive results, not evidence of absence of an effect	Yes	Unclear	No
25.	Using **confidence intervals** rather than post-hoc power analysis for interpreting the results of studies	Yes	Unclear	No
26.	Correctly interpreting **occurrence or association measures**	Yes	Unclear	No
27.	Distinguishing **causation** from association and correlation	Yes	Unclear	No
28.	Results of **pre-specified analyses** are distinguished from the results of exploratory analyses in the interpretation	Yes	Unclear	No
29.	Appropriate discussion of the **study methodological limitations**	Yes	Unclear	No
30.	Drawing only conclusions **supported by the statistical analysis** and no generalization of the results to subjects outside the target population	Yes	Unclear	No

STEP VI- SELLING THE PROPERTY (DISCUSSION)

- DISCUSSIONS
- **M**
- **M**
- **C**
- **L**

- DISCUSSION
- What do your results **M**ean?
- Are you **M**ethods successful?
- How do your findings **C**ompare to those of other studies?
- What are the **L**imitations of your study?

STEP VI- SELLING THE PROPERTY (DISCUSSION)

- DO NOT
- Re-write the results but correspond to it.
- Avoid unsupported grand statements – "*Will cure colon cancer once and for all".*
- Do not introduce new terms.
- Quantitative discussion NOT "minimal" or "higher involvement".
- Speculation based SOLELY on facts not your imagination.
- Compare published results that agree with yours BUT do not ignore work expressing contrary opinions. CONFRONT it and CONVINCE the reader that your work is better or correct.

STEP VII – PREAMBLE INTRODUCTION

- Address the problem that you are trying to solve.
- Are there any solutions if so which is the BEST solution?
- What are the limitations of the solution?
- What are you trying to achieve?
- Outline what you have done and presented in the very final paragraph.

STEP VIII– PREAMBLE ABSTRACT - TIPS

- The quality of the ABSTRACT usually influences the Editor’s decision.
- Precise and honest.
- Can stand alone.
- Is specific and brief.
- Avoids use of abbreviations.
- Cites no references.

STEP IX – PREAMBLE TITLE - TIPS

- THE BEAUTY OF BEING BRIEF.

- Specific.
- Concise.
- Complete.
- Conveys main findings of research.
- Attracts the reader.

STEP IX – PREAMBLE TITLE - TIPS

- AVOID REDUNDANCIES
- *“Preliminary Observations on the Number of Lymph Nodal involvement in different stages of Colonic Cancer and its effect on Overall Survival.” –*
- May be expressed in a more concise fashion---
- Relation between Number of Lymph Nodal involvement in different stages of Colonic Cancer and Overall Survival

THE EXTRAS– REFERENCES

- Must have been used in the article.
- Numbered consecutively.
- Personal communication and unpublished work should be mentioned in text.
- Please use full DOI links wherever available.

THE EXTRAS – REFERENCES - SOME SAMPLES

- Journal article
- Gamelin FX, Baquet G, Berthoin S, Thevenet D, Nourry C, Nottin S, Bosquet L (2009) Effect of high intensity intermittent training on heart rate variability in prepubescent children. Eur J Appl Physiol 105:731-738. https://doi.org/10.1007/s00421-008-0955-8

THE EXTRAS– REFERENCES - SOME SAMPLES

- Article by DOI
- Slifka MK, Whitton JL (2000) Clinical implications of dysregulated cytokine production. J Mol Med. https://doi.org/10.1007/s001090000086

THE EXTRAS– REFERENCES - SOME SAMPLES

- Book chapter
- Brown B, Aaron M (2001) The politics of nature. In: Smith J (ed) The rise of modern genomics, 3rd edn. Wiley, New York, pp 230-257

THE EXTRAS– REFERENCES - SOME SAMPLES

- Online document
- Cartwright J (2007) Big stars have weather too. IOP Publishing PhysicsWeb. http://physicsweb.org/articles/news/11/6/16/1. Accessed 26 June 2007

THE EXTRAS– REFERENCES - SOME SAMPLES

- Dissertation
- Trent JW (1975) Experimental acute renal failure. Dissertation, University of California

THE EXTRAS– REFERENCES -

- Always use the correct Abbreviations for the Journal.
- If in doubt refer to
- ISSN List of Title Word Abbreviations- • ISSN.org LTWA

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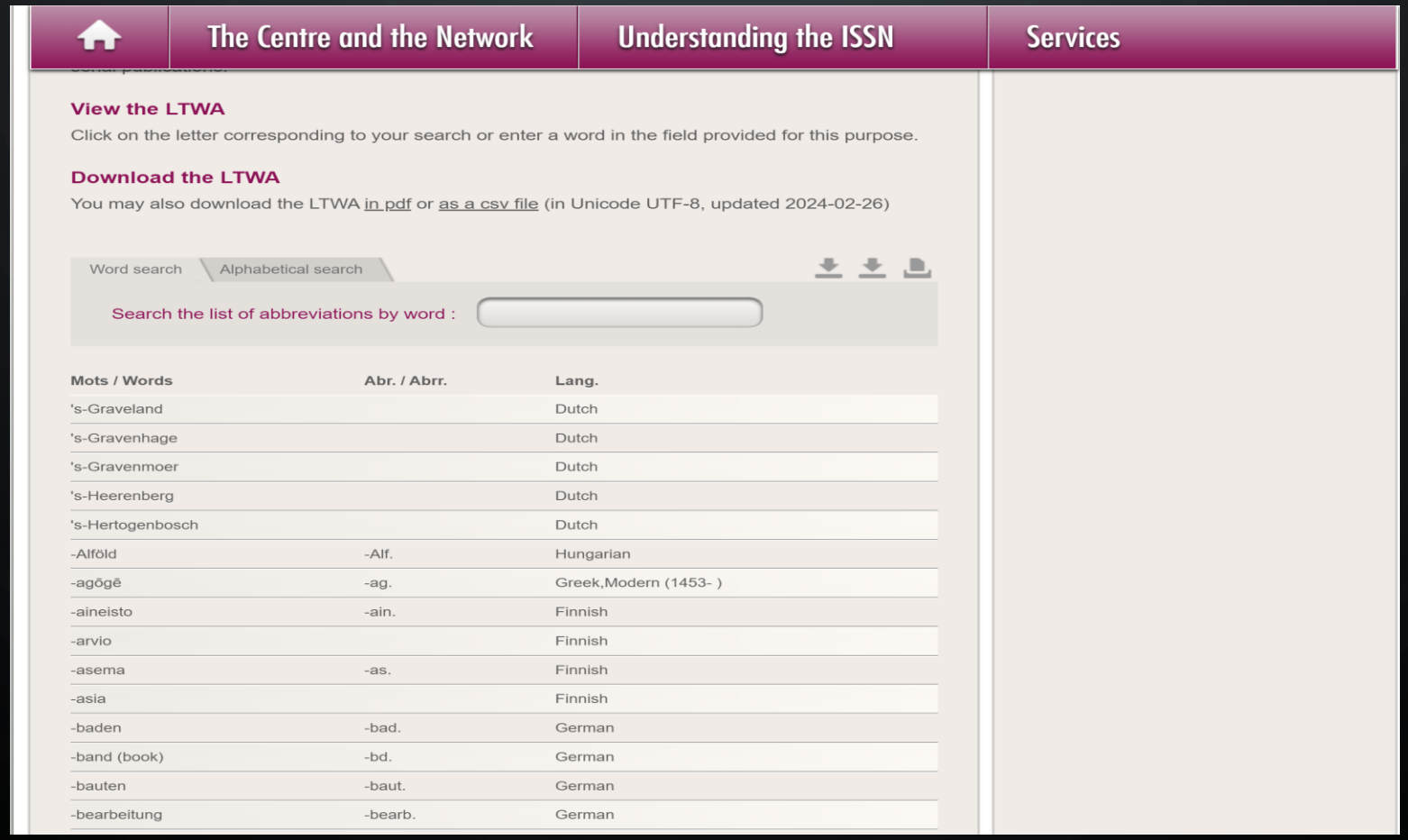

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Mots / Words	Abr. / Abrr.	Lang.
's-Graveland		Dutch
's-Gravenhage		Dutch
's-Gravenmoer		Dutch
's-Heerenberg		Dutch
's-Hertogenbosch		Dutch
-Alföld	-Alf.	Hungarian
-agōgē	-ag.	Greek,Modern (1453-)
-aineisto	-ain.	Finnish
-arvio		Finnish
-asema	-as.	Finnish
-asia		Finnish
-baden	-bad.	German
-band (book)	-bd.	German
-bauten	-baut.	German
-bearbeitung	-bearb.	German

THE EXTRAS – DISCLAIMERS AND ACKNOWLEDGEMENTS

- Acknowledgements of funds are According to Springer to be put on the Title page in a separate Section.
- One is obliged to reveal if any funding if any has been received for publishing the article.

FINALLY – THE COVER LETTER

- Editors Name – Good to address the Journal Editor BY NAME.
- First sentence –
  - Title
  - Author List and
  - Journal
- Description of
  - Research Area and Track Record.
  - Main findings of your research.
  - The significance of your research and why it would be relevant to the Journal.


Do not submit in multiple journals!!!!!!!
Sanjay D B