

Analysing yes/no clinical outcomes

Sarah Collin

Medical Statistician

Research and Development Support Unit

Outline

- Revision of adjustment
- Unadjusted analysis
- Relative risks and odds ratios
- Logistic regression
- Reading a paper
- Summary

Why do we need to adjust?

- Groups may not be balanced with respect to certain important factors
- In an attempt to control for confounding factors

Factors to adjust for

- Based on clinical (not statistical) knowledge
- Related to both outcome and the factor of interest
- Should be decided on at protocol stage
- Should be measurable at baseline
- Case-mix factor should not be on same 'causal pathway' as factor of interest
- Should not be too many

Yes/no outcomes

- Lived v died (survival analysis often better)
- Infection v no infection
- Condition v control
- Factor present v factor absent

Example without adjustment: Do u smoke after txt?

- Outcome: proportion quitting
- Explanatory factor: intervention (v control)
- Does the intervention have an effect on proportion quitting in the target population?

	Intervention N=854	Control N=838	P-value
Number quitting n(%)	239(28%)	109(13%)	<0.001

- Difference in proportions 15%(95%CI 11% to 19%)

Relative risk:

- In the paper they quoted relative risk
- $RR = 28\% / 13\% = 2.20$ (95% CI 1.79 to 2.70)

	Intervention N=854	Control N=838
Number quitting n(%)	239(28%)	109(13%)

Odds ratio:

- Odds of quitting = quit/not quit

$$\text{odds ratio} = \frac{239/615}{109/729} = 2.6$$

	Intervention N=854	Control N=838
Quit	239	109
Not Quit	615	729

Summary measures for binary outcomes

- Difference in proportions (risk difference)
- Risk ratio (relative risk)
- Odds ratio

Interpreting odds ratios

- Odds ratio = 1
 - No difference between groups
- Odds ratio > 1
 - Increase in odds (for treatment group compared to control) e.g. OR=1.1 means 10% increase in odds
- Odds ratio < 1
 - Reduction in odds (for treatment group compared to control e.g. OR=0.8 means 20% reduction in odds

Odds ratio

- Output of logistic regression
- Outcome 'quit' or 'not quit' lead to same conclusions
- Plausible model for risk
- Often misunderstood

Predicting bacterial cause in infectious conjunctivitis

Rietveld et al, BMJ
2004

Characteristic	Culture positive (n=57)	Culture negative (n=120)	Odds ratio (95% CI)
Mean (SD) age (years)	47 (17)	42 (14)	–
Median (range) duration of symptoms (days)	2 (1-7)	3 (1-7)	–
Female	36 (63)	68 (57)	–
History of hay fever	9 (16)	18 (15)	1.06 (0.45 to 2.54)
History of conjunctivitis	5 (9)	25 (21)	0.37 (0.13 to 1.01)
History of allergic conjunctivitis	3 (5)	6 (5)	1.06 (0.25 to 4.38)
Self treatment*	45 (79)	85 (71)	1.54 (0.73 to 3.26)
Redness:			
Peripheral	16 (28)	50 (42)	1
Whole conjunctiva	29 (51)	50 (42)	1.81 (0.88 to 3.74)
Conjunctival and pericorneal	12 (21)	20 (17)	1.88 (0.75 to 4.66)
Periorbital oedema	20 (35)	41 (34)	1.04 (0.54 to 2.02)
Secretion:			
None or water	20 (35)	47 (39)	1
Mucus	26 (46)	43 (36)	1.42 (0.70 to 2.90)
Purulent	11 (19)	30 (25)	0.86 (0.36 to 2.05)
Bilateral involvement	21 (37)	19 (16)	3.10 (1.50 to 6.42)
Itching	33 (58)	76 (63)	0.80 (0.42 to 1.52)
Foreign body sensation	23 (40)	48 (40)	1.02 (0.53 to 1.93)
Burning sensation	37 (65)	69 (58)	1.37 (0.71 to 2.63)
Glued eyes:			
None	5 (8)	33 (27)	1
One in the morning	30 (53)	74 (62)	2.68 (0.95 to 7.51)
Two in the morning	22 (39)	13 (11)	11.17 (3.49 to 35.77)

*Cleaning with water.

Logistic regression

- Outcome: binary variable
- Include explanatory factor + multiple case mix factors
- Use dummy variables for categorical factors (tell SPSS which factors are categorical)
- Get odds ratio + CI for odds ratio for explanatory factor

Example

- Population: pregnant women
- Sample: 8729 pregnant women from Aarhus, Denmark
- Question: Does low consumption of seafood effect birth weight?
- Outcome: birth weight (preterm delivery, growth retardation)
- Explanatory factor: consumption of seafood
- Case-mix factors: sex, smoking, alcohol, maternal age, parity, height, pre-pregnant weight, education, cohabitants

Table 4 Crude and adjusted* odds ratios (95% CI) for low birth weight, preterm delivery, and intrauterine growth retardation according to quantified daily intake of long chain n-3 fatty acids (n=7902). The highest intake group (QUANT5) is used as reference

Group†	Low birth weight	Preterm delivery	Intrauterine growth retardation
QUANT0:			
Crude	4.37 (2.43 to 7.87)	2.95 (1.67 to 5.20)	1.52 (0.91 to 2.55)
Adjusted	3.22 (4.73 to 6.00)	2.69 (1.49 to 4.84)	1.14 (0.67 to 1.98)
QUANT1:			
Crude	1.61 (1.02 to 2.55)	1.61 (1.09 to 2.37)	1.73 (1.31 to 2.28)
Adjusted	1.31 (0.82 to 2.10)	1.48 (0.99 to 2.21)	1.45 (1.09 to 1.94)
QUANT2:			
Crude	1.69 (1.07 to 2.68)	1.48 (0.99 to 2.21)	1.41 (1.05 to 1.90)
Adjusted	1.54 (0.97 to 2.46)	1.44 (0.96 to 2.16)	1.31 (0.97 to 1.77)
QUANT3:			
Crude	0.98 (0.60 to 1.61)	0.90 (0.59 to 1.38)	1.02 (0.76 to 1.38)
Adjusted	0.99 (0.60 to 1.63)	0.90 (0.59 to 1.39)	1.03 (0.76 to 1.40)
QUANT4:			
Crude	1.12 (0.67 to 1.88)	1.28 (0.83 to 1.96)	1.16 (0.85 to 1.59)
Adjusted	1.16 (0.69 to 1.94)	1.31 (0.85 to 2.01)	1.25 (0.91 to 1.72)
QUANT5:			
Reference	1.0	1.0	1.0
Statistical tests (dietary variable modelled as five indicator variables)			
Crude (P value)	0.0003	<0.0001	0.0003
Adjusted (P value)	0.004	0.003	0.09

*Adjusted for maternal smoking, alcohol consumption, age, parity, height, pre-pregnant weight, length of education, and cohabitant status (see text).

†See text for definitions of six groups.

Table 7 Crude and adjusted* odds ratios (95% CI) for low birth weight, preterm delivery, and intrauterine growth retardation according to fish intake (n=1159). The highest intake group (FREQ3) is used as reference

Group†	Low birth weight	Preterm delivery	Intrauterine growth retardation
FREQ0:			
Crude	4.06 (1.34 to 12.01)	3.79 (1.26 to 11.38)	1.28 (0.61 to 2.71)
Adjusted	3.57 (1.14 to 11.14)	3.60 (1.15 to 11.20)	1.01 (0.45 to 2.26)
FREQ1:			
Crude	1.60 (0.49 to 5.27)	2.34 (0.75 to 7.30)	1.44 (0.70 to 2.96)
Adjusted	1.39 (0.41 to 4.67)	2.09 (0.66 to 6.62)	1.26 (0.59 to 2.66)
FREQ2:			
Crude	1.26 (0.40 to 3.96)	1.59 (0.52 to 4.85)	1.01 (0.51 to 2.03)
Adjusted	1.25 (0.39 to 3.94)	1.58 (0.52 to 4.83)	1.02 (0.50 to 2.08)
FREQ3:			
Reference	1.00	1.00	1.00
Statistical tests (dietary variable modelled as three indicator variables)			
Crude (P value)	0.004	0.03	0.5
Adjusted (P value)	0.02	0.06	0.8

*Adjusted for maternal smoking, alcohol consumption, age, parity, height, pre-pregnant weight, length of education, and cohabitant status (see text).

†See text and table 5 for definitions of comparison groups.

Summary

- Logistic regression necessary to make adjustment when outcome binary
- Logistic regression gives outcome in terms of odds ratios
- Odds ratio is ratio of odds (not risk)