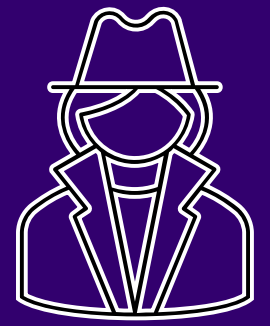
Quinolone Quandary: Fluoroquinolones and the Risk of Aneurysm and Dissection



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Disclosures

- I have no financial relationships or conflicts of interest to disclose.
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.
- I will not discuss off-label uses and/or investigational use in my presentation.

Abbreviations

FQ – Fluoroquinolone

AA – Aortic Aneurysm

AD – Aortic Dissection

RTI – Respiratory Tract Infection

GU – Genitourinary

SSTI – Skin and Soft Tissue Infection

GI – Gastrointestinal

IAI – Intra-abdominal Infection

CV – Cardiovascular

GUTI – Genitourinary Tract Infection

UTI – Urinary Tract Infection

AAA – Abdominal Aortic Aneurysm

AMS – Altered Mental Status

Poll 1

What is your current stance on FQ use and AA/AD?

A. Always avoid FQ if the patient has a history of AA/AD

B. AA/AD is so rare, no need to check for history of AA/AD before giving a FQ

C. Somewhere in between A and B

D. I'm not sure what my stance is

AA – Aortic Aneurysm
AD – Aortic Dissection
FQ - Fluoroquinolone

Objectives

- **Explain** what aortic aneurysm/dissection is
- **Describe** the historical context of concern with FQ causing aortic aneurysm/dissection
- **Identify** risk of aortic aneurysm/dissection with FQ use based on the literature
- **Discuss** literature strengths and limitations

Outline

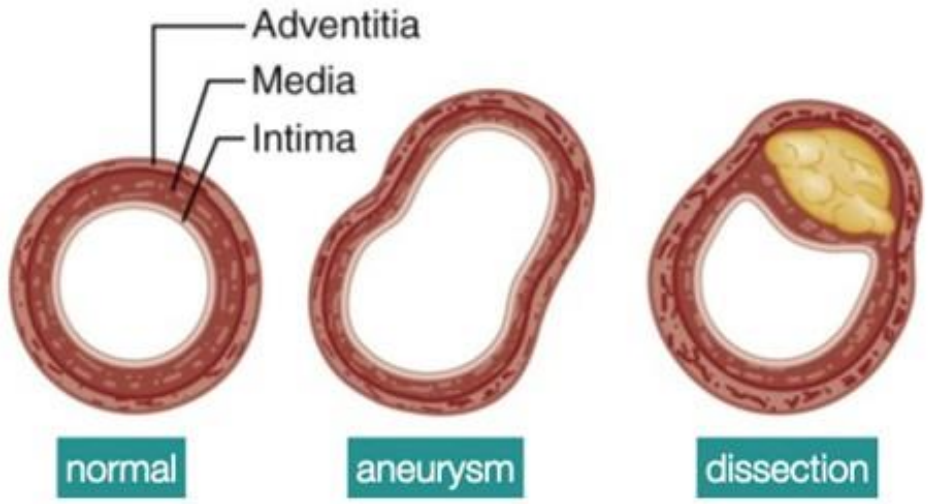
Background

Aortic Aneurysm/Dissection – Pathophysiology

Aneurysm: dilation of aorta, 1.5 times the expected normal

Dissection: separation of layers within aortic wall

Commonality: both caused by weakness of aortic wall from degradation of collagen fibers



Lee et.al. JAMA Intern Med. 175;11:1839-1847

Aortic Aneurysm/Dissection – Risk Factors

Risk Factors
Genetics (Ex. Marfan syndrome)
Gender (Males)
Age (> 65 years)
Aortic instrumentation or surgery (Ex. valve replacement, catheter insertion, etc.)
Cardiovascular disease (Ex. hypertension, atherosclerosis)
Pre-existing aortic aneurysm
Family history
Obesity
Inflammatory or infectious diseases causing vasculitis (Ex. syphilis, cocaine use, etc.)
Lifestyle (smoking)

Levy et.al. StatPearls
Rastogi et.al. Front Med. 9;814123

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Inflammatory or infectious diseases causing vasculitis (Ex. syphilis, cocaine use, etc.)
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JOURNAL ARTICLE

Infection and vasculitis FREE

Cristina C. Belizna, Mohamed A. Hamidou, Hervé Levesque, Loic Guillevin, Yehuda Shoenfeld

Rheumatology, Volume 48, Issue 5, May 2009, Pages 475–482, https://doi.org/10.1093/rheumatology/kep026

Published: 03 March 2009 **Article history** ▾

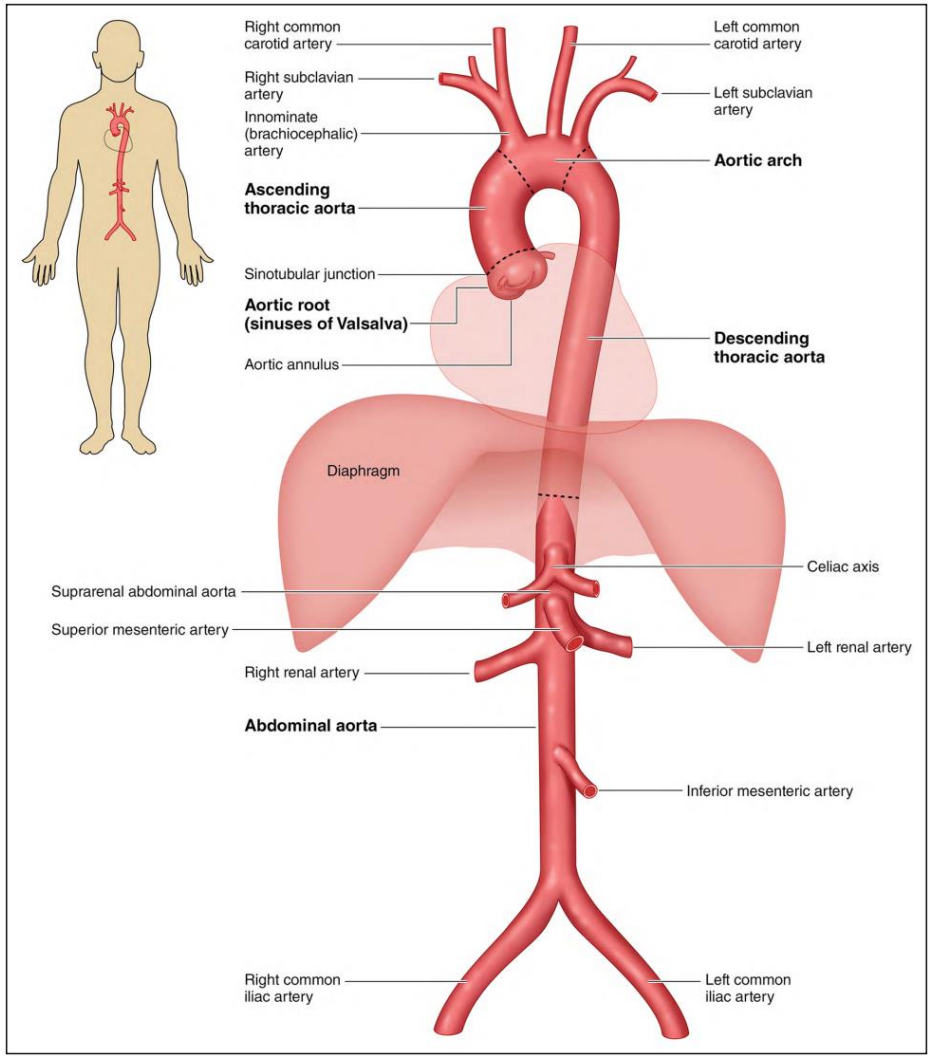
Levy et.al. StatPearls
Rastogi et.al. Front Med. 9;814123
Belizna et.al. Rheumatology. 48;5:475-482

Diagnosis – AHA 2022 Guidelines

- Asymptomatic
- Monitoring
  - Growth rate 0.3 to 0.5 mm/year
  - Monitor every 2 to 5 years

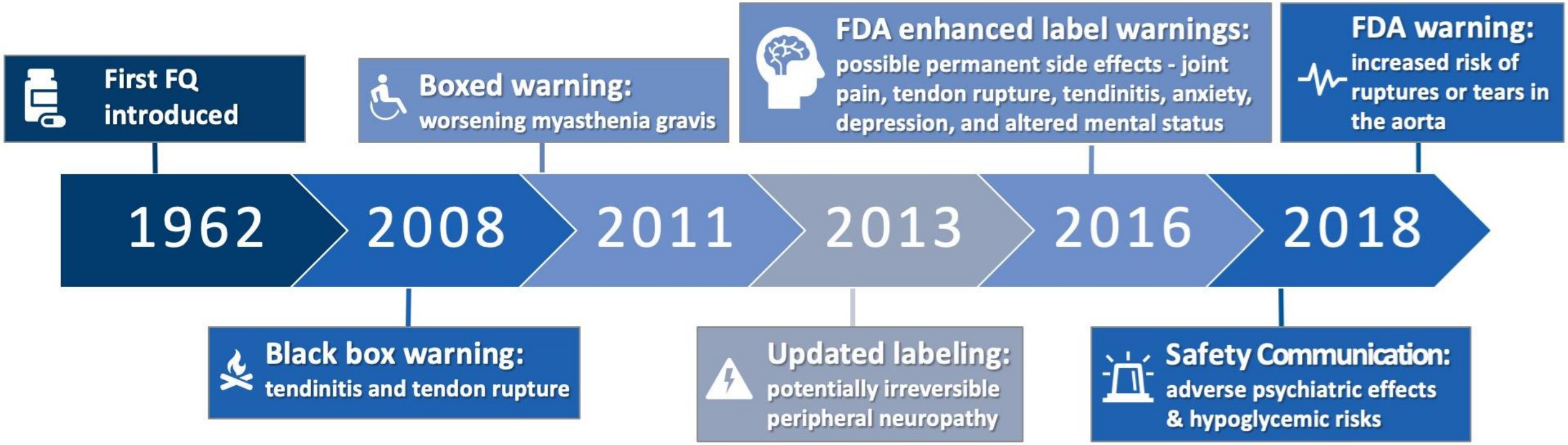
Anatomy	Diameter*
Abdominal aorta	Conventional definition (1.5 times expected normal)
Descending thoracic aorta	
Aortic root	Dilation: 4.0-4.4 cm
Ascending thoracic aorta	Aneurysm: ≥ 4.5 cm

*Adjust for BSA and sex



Henry et.al. J Am Heart Assoc. 14;7:e038821
Isselbacher et al. Circ. 146;24:e334-482

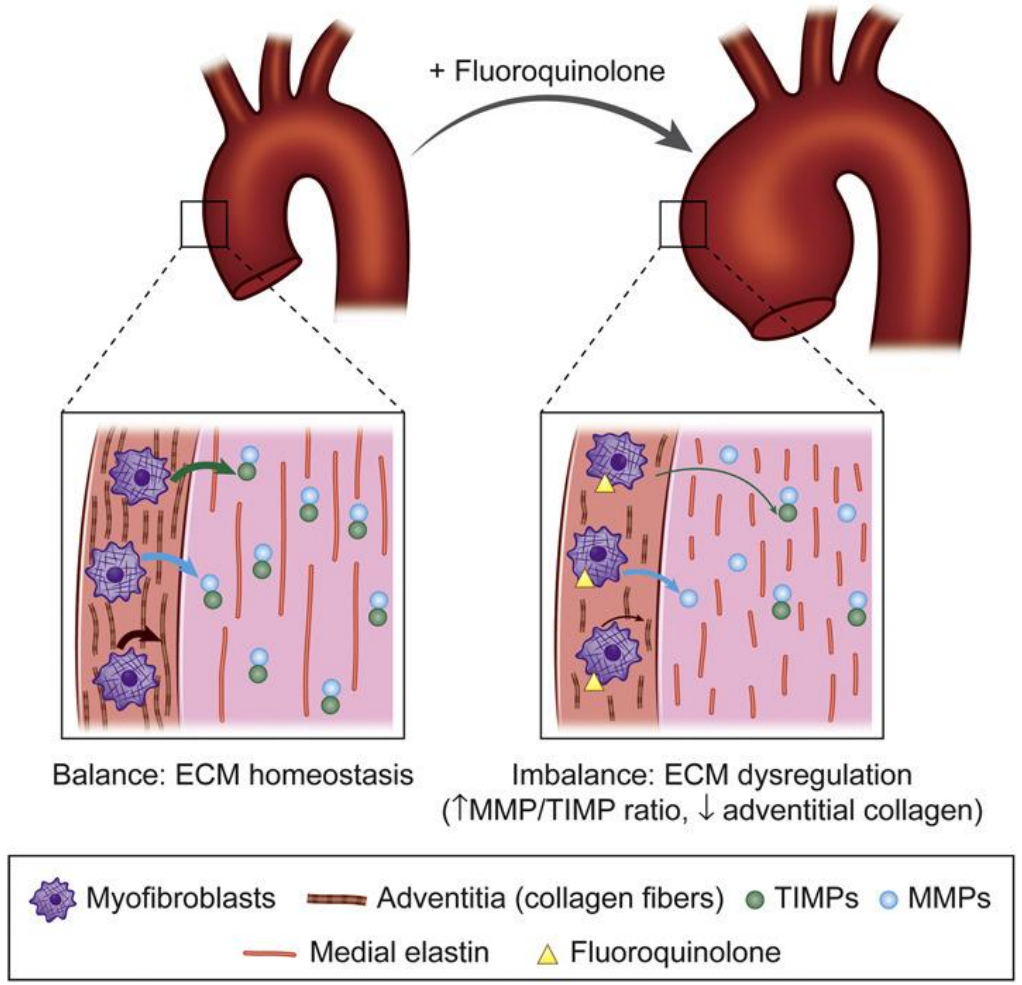
Fluoroquinolone – FDA Warning



Johnson et al. 135;7:828-835

Fluoroquinolone – Adverse Effect Mechanism

- Strong metal chelators → impair enzymes → inhibit collagen maturation → collagen degradation
- Collagen I and III are the major structural components in tendons, ligaments, and aorta



Reinhardt et.al. Angew Chem Int Ed Engl. 64;18:e202421424
Guzzardi et.al. J Thorac Cariovasc Surg. 157;1:109-119.e2

Case Application

CS 80 y/o M with PMH arthritis, hypertension, and aortic regurgitation presenting to ED for worsening cough and shortness of breath, diagnosed with pseudomonal pneumonia.

Is CS at increased risk for aortic aneurysm (AA)/aortic dissection (AD)?

Poll 2

Which of the following are risk factors for aortic aneurysm/dissection in CS?

A. Age > 65

B. Male sex

C. Arthritis

D. Hypertension

Explain what aortic aneurysm/dissection is

Poll 2

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Explain what aortic aneurysm/dissection is

Case Application

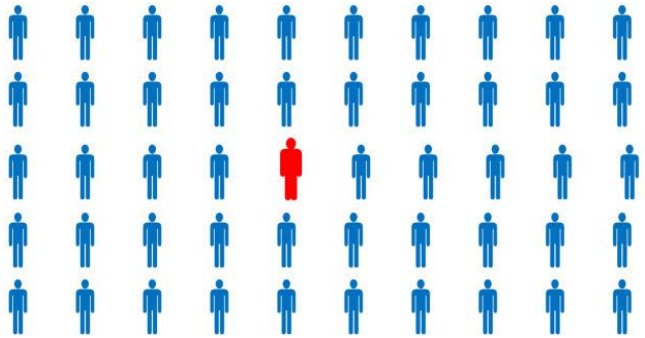
CS 80 y/o M with PMH arthritis, hypertension, and aortic regurgitation presenting to ED for worsening cough and shortness of breath, diagnosed with pseudomonal pneumonia.

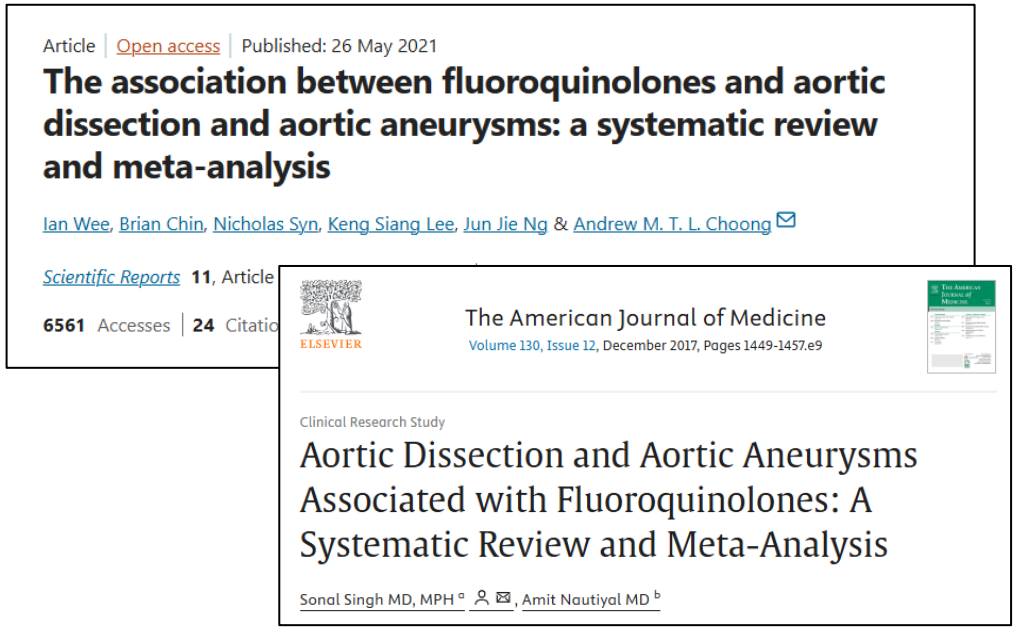
A routine TTE was recently done outpatient and found the aortic root to be dilated to 4.2 cm. The team is trying to decide whether to admit the patient for IV antibiotics or send home on oral levofloxacin.

Time to investigate!

Literature

Number-Needed-to-Harm





Article | Open access | Published: 26 May 2021

The association between fluoroquinolones and aortic dissection and aortic aneurysms: a systematic review and meta-analysis

Ian Wee, Brian Chin, Nicholas Syn, Keng Siang Lee, Jun Jie Ng & Andrew M. T. L. Choong

Scientific Reports **11**, Article

6561 Accesses | **24** Citatio

ELSEVIER

The American Journal of Medicine

Volume 130, Issue 12, December 2017, Pages 1449-1457.e9

Clinical Research Study

Aortic Dissection and Aortic Aneurysms Associated with Fluoroquinolones: A Systematic Review and Meta-Analysis

Sonal Singh MD, MPH [a], Amit Nautiyal MD [b]

Patient Population	Baseline Incidence of AA/AD (per 10,000 patient years)	FQ Associated Incidence of AA/AD (per 10,000 patient years)	Number-Needed-to-Harm	95% Confidence Interval
Adults (≥18 y/o)	1	19	7246	4329-14,085
Older adults (≥65 y/o)	13	N/A	618	518-749

Singh et.al. Am J Med. 130;12:1449-1457.e9
Wee et.al. Sci Rep. 11;1:11073
Pasternak et.al. BMJ. 360:k678

Study 1

Original Investigation FREE

Risk of Aortic Dissection and Aortic Aneurysm in Patients Taking Oral Fluoroquinolone

Chien-Chang Lee, MD, ScD[1,2,3]; Meng-tse Gabriel Lee, PhD[1]; Yueh-Sheng Chen, MD[4] ; et al

Author Affiliations | Article Information

RELATED ARTICLES FIGURES SUPPLEMENTAL CONTENT

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JAMA Intern Med
Published Online: November 2015
2015;175;(11):1839-1847.
doi:10.1001/jamainternmed.2015.5389

Risk of Aortic Dissection and Aortic Aneurysm in Patients Taking Oral Fluoroquinolone

Design	Retrospective nested case-control study from January 1998 to December 2011
Methods	Of 1 million individuals, 1,477 case patients were matched with 147,700 control cases from Taiwan's National Health Insurance Research Database (NHIRD) • Case patients: hospitalized for AA/AD • Control patients: matched for age, sex, and index date of case diagnosis • Exposure: FQ
Primary Outcome	Occurrence of AA/AD requiring hospitalization
Results	Table 2. Rate Ratios Associated With Aortic Aneurysm or Dissection, and Different Types of Fluoroquinolone Use

Fluoroquinolone Use[a]	Effect Estimate, Rate Ratio (95% CI)			
	Matched on Age Group, Sex, and Year	Adjusted by Individual Confounders	Propensity Score Adjusted	Propensity Score Matched
Current	2.93 (2.17-3.97)[b]	2.28 (1.67-3.13)[b]	2.43 (1.83-3.22)[b]	1.75 (1.11-2.74)[d]
Past	1.82 (1.44-2.29)[b]	1.49 (1.18-1.90)[c]	1.48 (1.18-1.86)[b]	1.19 (0.85-1.66)
Any use in prior year	2.11 (1.75-2.55)[b]	1.69 (1.39-2.06)[b]	1.74 (1.44-2.09)[b]	1.37 (1.04-1.79)[d]

Conclusion	FQ use is associated with increased risk of AA/AD

Investigation Questions

1. Was the control group also being treated for infection with antibiotics?
2. What were the indications for FQ?
3. Does longer duration increase risk?

Investigation Questions

1. Was the control group also being treated for infection with antibiotics?

   No; FQ vs. no FQ

Case Application

CS 80 y/o M with PMH arthritis, hypertension, and aortic regurgitation presenting to ED for worsening cough and shortness of breath, diagnosed with pseudomonal pneumonia.

CS is at increased risk for AA/AD for the following reasons:

- Risk factors (age > 65, male, hypertension)
- Lower number-needed-to-harm with older adults

Poll 3

Which of the following infections carries the greatest risk for aortic aneurysm or dissection?

A. Urinary tract infection

B. Lower respiratory tract infection

C. Skin and skin structure infection

D. Type of infection does not increase risk

Identify risk of aortic aneurysm/dissection with FQ use based on the literature

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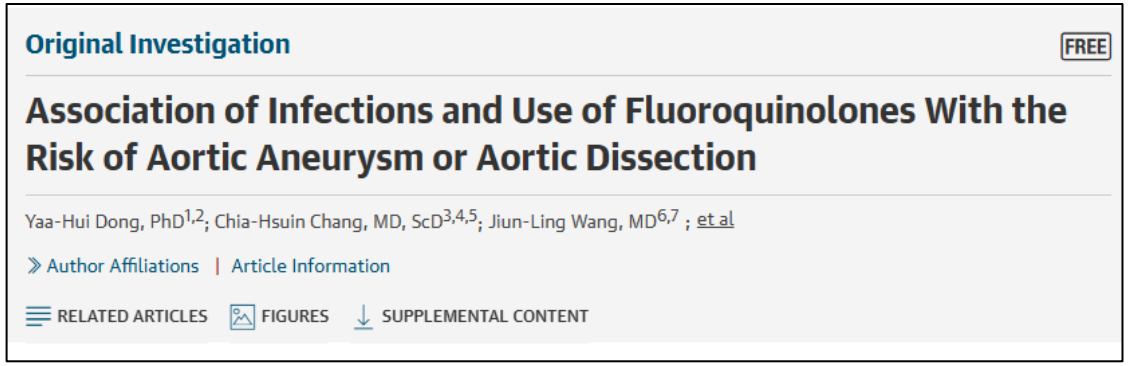
CS is at increased risk for AA/AD for the following reasons:

- Risk factors (age > 65, male, hypertension)
- Lower number-needed-to-harm with older adults
- Lower respiratory tract infection

Study 2


Original Investigation FREE

Association of Infections and Use of Fluoroquinolones With the Risk of Aortic Aneurysm or Aortic Dissection

Yaa-Hui Dong, PhD[1,2]; Chia-Hsuin Chang, MD, ScD[3,4,5]; Jiun-Ling Wang, MD[6,7] ; et al

» Author Affiliations | Article Information

RELATED ARTICLES FIGURES SUPPLEMENTAL CONTENT

Association of Infections and Use of Fluoroquinolones With the Risk of Aortic Aneurysm or Aortic Dissection	
Design	Nationwide nested case-control study from Jan 2009 to Nov 2015
Methods	Of 21,651,176 individuals, 28,948 case patients were matched with 289,480 control cases • Case patients: AA/AD • Control patients: matched for age, sex, and follow up duration • Exposure: infection and antibiotic use within 60-day risk window prior to AA/AD
Primary Outcome	Risk of AA/AD • Compared infections for which FQ are commonly used vs. no infection • Compared FQ with antibiotics with similar indication profiles
Results	See next slides
Conclusion	Concern for AA/AD should not deter FQ use

Dong et.al. JAMA Intern Med. 180;12:1587-1595

Study 2

Infection vs. no infection

Original Investigation FREE

Association of Infections and Use of Fluoroquinolones With the Risk of Aortic Aneurysm or Aortic Dissection

Yaa-Hui Dong, PhD[1,2]; Chia-Hsuin Chang, MD, ScD[3,4,5]; Jiun-Ling Wang, MD[6,7] ; et al

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RELATED ARTICLES FIGURES SUPPLEMENTAL CONTENT

Table 2. Risk of AA or AD Associated With Indicated vs No Indicated Infections

Infection type	No. (%) of participants		OR (95% CI)		
	Cases (n = 28 948)[a]	Matched controls (n = 289 480)[a]	Adjusted for matching factors[a]	Adjusted for matching factors and baseline covariates[a,b]	Adjusted for matching factors, baseline covariates, and concomitant antibiotic use[a,b,c]
Any indicated infections	5391 (18.62)	17 084 (5.90)	3.69 (3.57-3.81)	2.27 (2.19-2.36)	1.73 (1.66-1.81)
Specific indicated infections					
LRTI	1511 (5.22)	3891 (1.34)	4.54 (4.27-4.83)	2.78 (2.60-2.97)	2.11 (1.96-2.27)
GUTI	1665 (5.75)	5663 (1.96)	3.46 (3.27-3.66)	2.20 (2.07-2.34)	1.77 (1.66-1.89)
Skin, soft tissue, or bone infections	1049 (3.62)	5301 (1.83)	2.29 (2.14-2.46)	1.51 (1.41-1.62)	1.27 (1.18-1.36)
Intra-abdominal infections	174 (0.60)	346 (0.12)	5.92 (4.93-7.11)	3.99 (3.29-4.85)	2.99 (2.45-3.65)
Mixed infections[d]	759 (2.62)	1516 (0.52)	5.88 (5.38-6.43)	2.93 (2.66-3.22)	1.75 (1.57-1.95)
Septicemia	233 (0.80)	367 (0.13)	7.41 (6.28-8.74)	4.29 (3.59-5.12)	3.16 (2.63-3.78)
No indicated infection	23 557 (81.38)	272 396 (94.10)	1 [Reference]	1 [Reference]	1 [Reference]

Highest to lowest risk: Septicemia > Intra-abdominal > Lower RTIs > GUTIs > Mixed infections > SSTI/bone

Dong et.al. JAMA Intern Med. 180;12:1587-1595

Investigation Questions

1. Was the control group also being treated for infection with antibiotics?
2. What were the indications for FQ?
3. Does longer duration increase risk?

Investigation Questions

2. What were the indications for FQ?
    - Increased risk in more severe infections (Ex. lower RTI)
    - No increased risk for less severe infections (Ex. UTI)
    - Difference may be due to surveillance bias

Investigation Questions

1. Was the control group also being treated for infection with antibiotics?
2. What were the indications for FQ?
3. Does longer duration increase risk?

Study 3

Original Investigation

Oral Fluoroquinolone and the RiskofAortic Dissection

Chien-Chang Lee MD, ScD [a], Meng-tse Gabriel Lee PhD [a], Ronan Hsieh MD [b], Lorenzo Porta MD [c], Wan-Chien Lee MS [a], Si-Huei Lee MD [d e], Shy-Shin Chang MD, PhD [f]

Show more

Oral Fluoroquinolone and the Risk of Aortic Dissection	
Design	Case-crossover and case-time-control study from 2002 to 2011
Methods	1,213 hospitalized AA/AD included in case-crossover looking at exposure for the same patient across a **60-day period** prior to the AA/AD event vs. 60 day-referent period between 60-180 days prior to AA/AD
Primary Outcome	Incidence of AA/AD in relation to exposure
Conclusion	Exposure to FQ was associated with AA/AD

Table4. Duration-Response Analysis

Cumulative Fluoroquinolone Use	Exposed Individuals in Hazard Period (n=1,213)	Exposed Individuals in Referent Period (n=6,065)	Odds Ratio (95% CI)
<3days	1,192 (98.27)	6,017 (99.21)	Reference group
3–14days	14 (1.15)	32 (0.53)	2.41 (1.25–4.65)
>14days	7 (0.58)	16 (0.26)	2.83 (1.06–7.57)

Values are n (%), unless otherwise indicated.

Higher risk with prolonged exposure

Lee et.al. J Am Coll Cardiol. 72;12:1369-1378

Key Takeaways

To summarize…

Study	Takeaway	Limitation
1	Initial concern with using FQ arose from literature comparing FQ to no antibiotics or amoxicillin and found increased risk of AA/AD with FQ	FQ vs. no FQ or amoxicillin may not be optimal comparator
2	Further data indicates that infection may play a bigger role in increasing risk for AA/AD than antibiotic (some data to support increased risk in lower RTI and no increased risk in UTI)	Interstudy variability as to which infections carry greater risk and may be due to surveillance bias
3	Higher risk with increased durations of >14 days vs. 3-14 days	Low incidence of AA/AD and small population may introduce selection bias

Key Takeaways

1) There is biological plausibility to explain association between FQ and AA/AD
2) Conflicting outcomes described in the literature
    a) Evidence supporting infection as a risk for AA/AD rather than FQ
    b) FQ use should not be avoided if clinically indicated
3) Limited studies evaluating “high risk” populations
    a) Genetic conditions
    b) Pre-existing AA/AD

Risk Factors
Genetics (Ex. Marfan syndrome)
Gender (Males)
Age (> 65 years)
Aortic instrumentation or surgery (Ex. valve replacement, catheter insertion, etc.)
Cardiovascular disease (Ex. hypertension, atherosclerosis)
Pre-existing aortic aneurysm
Family history
Obesity
Inflammatory or infectious diseases causing vasculitis (Ex. syphilis, cocaine use, etc.)
Lifestyle (smoking)

Key Takeaways

How to approach FQ use in “high risk” patients:

1) Avoid with aortic diameter ≥ 4.5 cm
2) Avoid in patients with genetic aortopathy
3) Risk vs. Benefit
4) Use shortest duration possible

<u>Future Studies</u>

- Lack of high-quality studies investigating growth rate and advanced biomarkers

Henry et.al. J Am Heart Assoc. 14;7:e038821
Gardikioti et al. Life. 14;8:992
Makiura et al. JTCVS Tech. 33:51-57

Case Application

CS 80 y/o M with PMH arthritis, hypertension, and aortic regurgitation presenting to ED for worsening cough and shortness of breath, diagnosed with pseudomonal pneumonia.

A routine TTE was recently done outpatient and found the aortic root to be dilated to 4.2 cm. The team is trying to decide whether to admit the patient for IV antibiotics or send home on oral levofloxacin.

Poll 4

What will you tell the team?

A. Admit the patient for IV antibiotics

B. Send home on oral levofloxacin

C. This is a difficult decision. I'm not sure!

Case Application

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Acknowledgements

Jeannie Chan, PharmD, MPH

Zahra Kassamali Escobar, PharmD, BCIDP

Candice Wong, PharmD, BCPS

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Questions?

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